APPENDIX W

Comments and Responses on Public Review Draft, July 2000

Comments and Responses on:

Public Review Draft
Human Health Risk Assessment for the
Coeur d'Alene Basin Extending from Harrison to
Mullan on the Coeur d'Alene River and Tributaries
Remedial Investigation/Feasibility Study
July 2000

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SECTION 1.0
DOCUMENT ORGANIZATION

1.0 DOCUMENT ORGANIZATION

The following document contains comments and responses to the *Public Review Draft of the Human Health Risk Assessment for the Coeur d'Alene Basin Extending from Harrison to Mullan on the Coeur d'Alene River and Tributaries.* State/EPA received comments from several organizations and individuals. This document is a compilation of comments and response from various individuals and organizations. This section summarizes the contents and organization of this document, as follows:

- Section 2 contains a general response to comments that address global issues rather than specific comments.
- Section 3 contains Dr. Paul Mushak's responses to comments. Dr. Mushak provided an independent peer evaluation of the comments and is a consultant to EPA Region X.
- Section 4 contains the Technical Review Workgroup for Lead's (TRW) comments on the risk assessment. The TRW is an interoffice workgroup convened by the USEPA Office of Solid Waste and Emergency Response/Office of Emergency and Remedial Response (OSWER/OERR). Its goal is to support and promote consistent application of the best science in the field of lead risk assessment at contaminated sites nationwide.
- Section 5 contains responses to specific comments from each of the commentors. The comments were responded to by State/EPAs "Lead Contractor," Terragraphics (TG), or State/EPAs "Nonlead Contractor," URSCorp (URS). The comments and responses are arranged as follows:

    Each row contains a specific comment and it's response. The comments are in the left-hand column and the responses are in the right hand column. At the top of each row will be the Comment ID, the Comment Date, the commentor and his organization, the response due date, the respondent, and the status of the response (i.e., accepted, partially accepted, or not accepted). In general, an accepted response will trigger revisions to the next draft of the document; a partially accepted comment is one with which the State/EPA partially agrees, but may or may not be addressed in the revisions to text in the next draft of the document (the individual comment response notes whether text changes will be made); and a comment that is not accepted is one with which the State/EPA disagrees, no changes will be made to the document, and an explanation is provided in the responses.

SECTION 2.0
GENERAL RESPONSES TO COMMENTS

Human Health Risk Assessment for the Coeur d'Alene Basin Extending from Harrison to Mullan on the Coeur d'Alene River and Tributaries - Public Review Draft , July 2000

Response to Comments

The various written comments received and notes taken regarding discussions and questions during public meetings and presentations have been entered into a database as specific comments and concerns. Individual responses to each of the specific written comments received from the public and interested parties are included in the database. Those comments together with particular concerns expressed during meetings, conference calls, group discussions, and presentations have been summarized below in eleven general categories. A general response is provided following each comment category.

Also included as part of the response to comments are i) an independent peer evaluation of comments prepared by Dr. Paul Mushak, consultant to EPA Region X, and ii) the Technical Review Workgroup for Lead (TRW) evaluation of the HHRA.

Public Comment and General Response Categories

1 Comments Related to Population Demographics and Socio-economic Factors: Several comments addressed the socio-economic and demographic aspects of lead exposure. Comments included comparisons of the incidence of high blood lead levels to other populations with similar socio-economic characteristics, considerations in evaluating children with high blood lead levels, and how poverty-related factors might influence risk management decisions. Comments noted the incidence of poverty among children in the Basin was twice the State average, that socio-economic factors may influence many of the assumptions and parameters used in quantitative analysis of lead exposure, that the importance of the mining industry in the local economy was understated, that the potential for tourism was overstated, and suggested probable difficulties with developing new businesses during an extended Superfund project. Other comments urged that risk managers pay more attention (than believed typical for Superfund projects) to socio-economic issues in formulating risk-reduction strategies. Some comments indicate that the situation with respect to blood lead levels in the area is "relatively good" in consideration of the poverty levels, long history of mining activities, and comparison to other economically disadvantaged areas in the nation. Many comments addressed future risk reduction strategies questioning whether poverty initiatives can significantly reduce blood lead levels, that excess absorption is not isolated to disadvantaged families as not-so-poor children are also observed with high blood lead levels, and that health intervention efforts might be more effective than source cleanup in addressing lead poisoning. Other comments, conversely, suggest that those same poverty-related factors could make intervention efforts less effective, and that more source cleanup might be required.

1a General Response Regarding Demographics and Socio-economic Factors: *Comments received regarding demographic data generally did not dispute the data presented, but did provide suggestions regarding the interpretation of this information for risk assessment and eventual management activities. Demographic characteristics for the geographic portion of the Basin addressed in the HHRA are discussed in Section 3.1.2. The primary references were the 1980 and 1990 Census and updates, Idaho Department of Commerce publications, Idaho Kids Count: Profiles of Child Well-Being, and data provided by Public School Districts 391, 392 and 393. This area's economy has undergone significant changes in the last two decades that have had major impacts on local demographic factors that influence lead exposure. Total employment, according to census data in Shoshone County, for example, is down by 27% from 9126 jobs in 1980 to 6663 in 1996. Mining jobs decreased from 27% of total employment in 1980 (2465 jobs) to less than 10% (or 642 jobs) in 1996. These changes have been followed by out-migration of young families that has resulted in a continuing loss of young children. Overall population decreased by 30% from 1980 to 1990. The median age of the population changed from 27 years in 1970 to 39 years in 1998. Since 1990, the number of preschool children in the County has decreased by 12% compared to a 7.7% decrease among older children. Little new housing construction has occurred in the last two decades and median age of housing in several census tracts pre-dates World War II.*

Similar to many other lead contaminated sites, these and other socio-economic factors play an important role in the prevalence and degree of lead poisoning in the Basin. The HHRA notes that nearly one-third of the children in the Basin are growing up in poverty by federal government definitions. Poverty and lead poisoning interact in several ways. Children may have lowered nutritional status and live in poorer quality housing. Parents may experience more difficulties in managing the home and children and are less able to provide a stimulating and healthy home environment. Behavioral and home and child hygiene co-factors can lead to increased ingestion rates of soils and dusts. Yard soils and house dust can be more contaminated due to deteriorating lead paint, proximity to industrial sources, and lesser quality maintenance of the home, yard and local infrastructure. The age of housing in the Basin is problematic due to the frequent use of lead paint and accumulation of contaminated dusts throughout the last century. As a result, poor children ingest more soil and dust that has a higher lead content. These children tend to absorb more of the ingested lead than more nutritionally sound children, resulting in higher blood lead levels. In addition, poor children are then more vulnerable to adverse health effects resulting from their lower general health status, reduced access to quality health care, and early childhood educational opportunities.

Several comments urged that risk reduction efforts, that could address problems associated with poverty in the area, be considered in the development of risk management strategies. Many, if not most, of these lead source and socio-economic factors are common to the BHSS, located in the center of the Basin. Experience gathered at the BHSS and through the Lead Health Intervention Program in the Basin can be useful in assessing these children. These results suggest that following the cleanup efforts in the "Box", the children with high blood lead levels are young, are often exposed to sources outside the home environment, and have accompanying *socio-economic difficulties. In the 2000 Lead Health surveys, only six children (<3%) over 3 years of age showed blood lead levels greater than 10 ug/dl in the "Box". In the Basin, 7% or 8 children in this age range showed high levels. However, in children aged 1-3 years, 11% in the Box and 14% in the Basin showed excess absorption in 2000.*

The greatest incidence of levels exceeding 10 ug/dl in 2000 was in the youngest 9-24 month aged group. This result suggests exposure to house dust levels in the principal activity areas of the home and home yard, or soil/dust exposures in locations away from the residence. Both sources seem to be indicated in these children's follow-up investigations. In most cases, these exposures are aggravated by socio-economic factors related to poverty. Overall, these findings suggest the most effective strategy to reduce risk for these young children should target reducing dust lead loading in the home and those socio-economic factors that aggravate lead absorption for these disadvantaged families. House dust studies in the Box and in the Basin show dust lead loading is related to several factors including overall community soil lead levels, home yard lead levels, interior paint condition and paint lead concentration, home hygiene practices, and exterior soil cover. Several of these factors are inter-related to socio-economic conditions that exacerbate lead exposure and absorption problems. Some comments urged risk managers consider poverty-related factors in developing cleanup plans. Potential risk reduction remedies that have been applied at other sites to reduce dust lead loadings and help to alleviate socio-economic co-factors that influence blood lead levels include:

- *Soil Abatement*
  - *Includes yard soil, community soil areas and specific fugitive sources removals to reduce direct exposure and a primary source of lead to house dust.*
- *Paint Abatement*
  - *Includes stabilizing interior and exterior lead based paint in homes of poor condition.*
- *Household Assistance/Select Cleaning*
  - *Includes providing vacuum cleaners loaners to homes without adequate vacuums, assistance in certain circumstances, and possible one-time cleaning.*
- *Screening*
  - *Includes voluntary blood lead screening services with provision for self-initiated testing at any time.*
- *Public Nursing*
  - *Includes follow-up services for all high blood lead level children, general advice and consultation and specialized assistance on a case-by-case basis.*
- *Access to other programs*
  - *Includes referrals to other social, housing and medical assistance programs that offer complimentary services for needy families.*
- *Community Development Poverty Initiatives*
  - *Includes assistance to and support of community development initiative to attract new industry and business to the Basin.*

-Job Training

- Includes assistance to job training programs to ensure local hiring for cleanup activities and enhance employment opportunities for Basin residents.

- Early Periodic Screening and Diagnostic Testing(EPSDT)

- Includes addition of blood lead screening and lead health related testing and diagnostic services to Medicaid programs among local service providers.

-Medicaid

- Includes assistance in securing appropriate Medicaid benefits for eligible young families throughout the Basin.

-Young Family Programs

- Includes development of educational programs for young parents alerting them to available health, educational, housing, and income resources.

-Preferential Hiring

-Includes adoption of appropriate rules and regulations to ensure local preference in hiring for any publicly funded cleanup activities.

-Developing clean play areas

- Includes cleanup of existing, and developing new recreational areas that will be accessed by young children to residential cleanup criteria.

-Water Subsidies

- Includes community and individual subsidies to provide water for dust control and maintenance of vegetative cover.

-Community Greening

- Includes grants and subsidies to promote vegetative cover throughout local communities.

-Housing Initiatives

- Includes support of paint abatement programs, assistance with remodel and cleanup activities that reduce lead health risk through home/yard improvement.

-City/County Public Works Assistance

- Includes assistance to communities that operate and maintain infrastructure critical to dust and storm water runoff control.

-Supplemental Water Source Development

- Includes assisting communities to develop supplemental water supplies to ensure dust control and vegetative barrier maintenance during drought periods.

-Curb/Gutter Storm water Infrastructure

- Includes curb and gutter installations to reduce dust generation, right-of-way contamination, and enhance dust control efforts.

- Includes supplementing existing storm water collection and containment systems to enhance dust and sediment control in communities.

- Includes assistance with facilities and operation and maintenance of snow removal activities to reduce aggravation of contaminated dust and sediment problems in communities.

-Parks/Playgrounds/Pools

- Includes development of alternate play areas and water-based recreation facilities to encourage families with young children to recreate in clean areas.

-Community Resource Centers

- Includes development of community resource centers for young parents that can dispense social and health services in an encouraging and constructive atmosphere.

2 Comments Related to Blood Lead and Exposure Surveys in the Basin: Several comments addressed the low turnout of children in the exposure and blood lead surveys conducted in the last four years. These comments indicate that the results of these surveys may misrepresent the extent and degree of lead intoxication in the Basin. Many of those comments contend that socio-economic biases may be inherent in the self-selected population presented for blood lead sampling. However, comments differed in opinions and conclusions with regard to the potential bias. Some reviewers believe solicitation incentive programs (paying $20-$40 per child for blood) result in a disproportionate number of poor individuals participating. These arguments suggest that socio-economic factors are well-correlated with blood lead levels, mask the true effects of contaminated media, and exaggerate the incidence of lead poisoning in the community. Other comments suggest that those that volunteer for blood lead testing are more informed regarding lead poisoning issues, more inclined to benefit from the intervention services, more attentive to health issues and, as a result, show lower blood lead levels than those that were not tested. Some comments also point out that socio-economic conditions in the area over the past two decades have led to age biases in the population that influence the degree of lead intoxication noted in the health surveys. These comments note that there has been a 12% decrease in young children in the past ten years and this age-group is greatly under-represented in blood lead surveys.

2a General Response Regarding Blood Lead and Exposure Surveys: *Several comments speculated that poverty-related factors influence and, possibly, distort the incidence of high blood lead levels in the Basin. Available data indicate that about one-in-four children under two years of age have blood lead levels of 10 ug/dl or greater, and the age adjusted incidence of excess blood lead levels is 16.2% for 1-6 year-old children. This incidence of high blood lead levels is a health concern for these children. There are divergent opinions as to how well the health surveys represent the non-participants and whether comparisons to other national and State populations are appropriate. Comparison of blood lead data for the Basin to other sites and national or State-wide surveys, for the purpose of determining whether these findings are "relatively good or bad", is problematic. Such large data sets (i.e., National Health and Nutrition Examination Survey (NHANES)), for various technical reasons, cannot be used to compare and draw conclusions about the relative degree of health hazard existing for children in the Basin communities. Scientific designs of the NHANES surveys, are constructed in a way that does not allow simple comparisons with results of blood lead distributions for a single community. NHANES data provide a current snapshot for numerous national subsets or strata,* *that may not be appropriate for any single community. An explicit warning on technical grounds against making such comparison is in the Executive Summary of ATSDR's 1988 report to Congress on childhood lead poisoning in America (ATSDR 1988). Additionally, the purpose and design of the Basin surveys were conducted in a manner that does not match the organization of the various demographic and socioeconomic strata in the NHANES III survey reports (e.g., race/ethnicity, income, housing age).*

With regard to the Basin-wide survey, selection bias may have occurred related to individual family decisions to participate. One argument suggests that the incidence of lead poisoning is likely greater among non-participants, as families that did participate are more attentive to lead poisoning and have benefitted from the local health department's efforts to assist parents in reducing exposures. A counter argument suggests that paying each child $40 as an incentive in the 1999 survey favored low-income participation. Because potentially high exposures are associated with poverty-related factors, higher than average blood lead concentrations would be expected among the participants. The HHRA did not draw a conclusion relative to these arguments as there are not sufficient data to test either hypothesis. These issues are discussed in Sections 6.2.2 and 7.4.1, 8.8, and 8.11.2 and reflect most of the comments offered by reviewers.

Several comments requested additional characteristics regarding the number of children contained in the blood lead database for the Basin. A total of 524 blood lead observations were compiled in four surveys from 1996 to 1999. There were 424 individual children from 247 households. Eighty-one (81) children from 57 homes were tested more than once. Sixty-five (65) of those children were tested twice, 13 were tested three times and 3 were tested in each of the four years. Of those children tested more than once, 11 had levels greater than 10 ug/dl and received intervention services from the local public health program. Seven (7) of these children had lower blood lead levels in subsequent testing, 1 had the same level, and 3 had higher levels. The children tested more than once tended to have lower than average levels for children in their age group on the first test and similar levels on subsequent testing. Of the 81 children tested more than once, 21 had higher than average blood lead levels for their age group, 51 had lower, 9 had average levels. These results would indicate that some observations used in the analysis were lower than might be obtained in a random sampling of the population. It is estimated that there are between 1000 and 1100 children from 9 months to 9 years of age in the Basin area. In 1999, 272 or slightly more than 25% of these children were tested. In other years less than 20% of eligible children participated. The Bunker Hill Superfund Site participation rates have been estimated from 51% to 58% of the population annually over the last decade. Table 1 summarizes the participation rates.

Comments have suggested that the socio-economic co-factors describing the blood lead population be compared to that of the overall population. There is not, however, a complete socio-economic database for these children that would allow for such a comparison of risk co-factors. However, the environmental source characteristics can be compared, as shown in Table 2. These results indicate that the source variables for the blood lead population are similar to *that of the general population. Table 2 also shows that there is disparity with respect to the number of paired observations by geographic sub-area.*

3 Comments Related to the Use of Site-Specific Data: There were several comments regarding the use and analysis of site-specific data in the HHRA. These comments addressed the definition and characterization of site-specific data and analysis, whether ingestion and contact rates appropriate to the Coeur d'Alene Basin were employed in the HHRA, whether appropriate dust sampling techniques were employed, and critiques regarding specific relationships and model parameters. Some comments were critical of the combination of soil contamination data from different surveys, the sieve size used in processing soil and dust samples, and the relationship between paint, soil, dust and blood lead levels. Comments were also received noting that confidentiality requirements necessary to protect individuals participating in public health service programs preclude independent evaluation of the findings of the HHRA with respect to site-specific analysis and assessment of individual behaviors and lifestyles contributing to high blood lead levels.

3a General Response Regarding the Site-Specific Data Analysis: *Site-specific analysis, as defined for this HHRA, involves the collection of actual blood lead data from the resident population and relating those observations to measured concentrations in environmental media. Existing blood lead data are summarized in Section 6.2 and site-specific quantitative analysis is presented in Section 6.4. Site-specific analysis of risk for this particular HHRA was conducted using the data available from recent surveys and investigations supplemented by additional sampling efforts conducted in November of 1999. This analysis was undertaken in response to Potentially Responsible Parties (PRP), State and local government, and public requests that actual blood lead levels and environmental data from the Basin be considered in assessing risk and identifying risk reduction strategies. The PRPs and local public interest groups also requested that specific evaluation of lead paint data previously obtained, but not analyzed in the 1996 Exposure Study, be recovered and used in these evaluations. The site-specific analysis helps to establish that percentage of the population that is actually experiencing lead poisoning and characterize the direct link between lead in blood and the various sources. This is generally accomplished by conducting well controlled investigations that collect both blood lead and environmental source data and relating those through statistical techniques. In this case, only the 1996 Basin Exposure Study was designed to support such analysis. Although a large residential environmental sample and exposure database was obtained in 1996, few children provided blood lead samples. Based on the results of the 1996 study, considerably more children were solicited in subsequent blood lead surveys and a strategy was developed of combining these results and conducting supplemental environmental sampling to complete a paired blood lead/environmental exposure data set to support site-specific analysis. This approach has been used at other Superfund sites and is consistent with EPA guidance. EPA guidance does require that any site-specific analysis be based on compelling scientific evidence, collected in controlled investigations that are representative of the population of concern, the contaminated media, and the routes and pathways of lead exposure that are, or could be, occurring in the future. A non-confidential form of the paired blood lead and environmental exposure data set will be included* *as an Appendix to the final document. All individual identifiers have been removed and categorical values developed to replace actual concentrations to protect the confidentiality of the data and privacy of families supplying information.*

3b General Response Regarding Use of Blood Lead Data in Site-specific Analysis: *Many of the comments received suggest that the blood lead data are not representative of that portion of the population that did not participate in the blood lead surveys. The representativeness of the blood lead data set is discussed in General Comment # 2a The site-specific dose-response analysis conducted in the HHRA are reflective of those paired observations of blood lead and environmental exposure in the assembled database. As a result, the findings and conclusions are applicable to the population studied. The environmental exposures in the site-specific database are believed to be representative of the typical conditions throughout the Basin. There has been speculation in various comments that the blood lead information may be biased. Arguments have been presented for both high and low biases. The effect of these biases, if any, is unknown.*

3c General Response Regarding Use of Soil Lead Data in Site-specific Analysis: *With respect to environmental data, the effects of combining soil metal concentration results from different surveys were assessed in Appendix N to the HHRA. This analysis concluded that there were not substantive differences in surface soil sampling results from different surveys. Approximately 2400 homes in the Basin were estimated in the 1996 survey census to have potential residential soil contamination associated with mineral industry releases. Approximately, 40 % or 1020 of these homes have been sampled. Comments were received objecting to the use of surface soil contamination data in exposure characterization. Some comments indicated that sub-surface results should be used, as children are known to dig in play activities. Sub-surface soils are characterized in the HHRA in Section 6.6. These concentrations are used in assessing occupational risk to workers that might be involved in excavation activities. Surface soil concentrations are used in all residential and recreational exposure estimates as these are the soils most likely to be encountered in these activities and the soils most susceptible to transport and migration. This approach is consistent with current guidance and is routinely applied in risk assessments throughout the country. Risk managers are cautioned to remember that children do dig during play activities and to consider remedies protective of this potential pathway in developing risk reduction strategies.*

There are potential differences in soil lead levels between the Basin results and those from other sites on the basis of the sieve size used to process soil samples. Comments were received criticizing the HHRA for using soil samples sieved to minus 175 micron. Some comments favored the more coarse 250 micron sieve recommended in recent EPA guidance and others favored a finer sieve used for sediment characterization by the U.S. Geological Survey (USGS) in ecological/transport evaluations. The 175 micron mesh sieve technique was adopted in 1974 for the original lead health studies conducted in the area and has been used for all residential soil samples collected in the Basin RI/FS and all previous health and exposure studies. The procedure was developed to reflect the range of soil particle size most likely to adhere to children's hands and be involved in hand-to-mouth activities. Subsequent research has continued *to show that this size-range is applicable. The selection of this standard pre-dates either recommendation from federal agencies, and the State Department of Health and Welfare has elected to maintain consistent soil and dust measurement techniques throughout the course of these investigations. The EPA has concurred in that determination. No data have been collected to assess the difference, if any, among these size fractions for residential soils or house dust. Evidence and experience from other sites would suggest that smaller particle size fractions could exhibit higher concentrations of lead and other metals. If this were the case, lead concentration in soil and dust measured in the Basin might be lower using the sieve size suggested by the EPA or higher using that suggested by USGS. Assuming any concentration effect due to sieving is proportional, the use of lower value (as suggested with EPA's larger sieve size) could result in an increased dose response coefficient in the site-specific analysis. That is, the per unit effect of soil or dust lead concentration on blood lead levels would be greater. This would be interpreted as indicating higher bioavailability of soil and dust or lesser intake is occurring in the population. Using higher concentrations that might result from smaller sieve sizes would produce the opposite effect and conclusions. Provided the effect is proportional, it is of little consequence in the empirical site-specific analysis, as the coefficients relating blood lead to environmental variables would adjust accordingly. In relation to applications of the IEUBK model and comparisons to other sites, differences could be significant. It is important that risk managers use equivalent procedures in developing and designing risk reduction strategies involving measurement or evaluation of soil and dust lead concentrations.*

An additional comment questioned combining flood plain soil and sediment data in the Lower Basin, suggesting that soil and sediment could be independent data sets and do not have sufficient statistical similarity to justify combining. For some sites, upland soil and beach sediment data may be statistically different for some contaminants. This may be an important issue in defining the nature and extent of contamination. However, due to the assumptions used in calculating risk, any differences in sample means is accounted for in the estimation of exposure point concentrations. The soil and sediment data were appropriately combined for the Lower Basin neighborhood and public receptors for several reasons. The "upland" areas had all been impacted by previous flood events, and experienced a mixing of soil and sediment materials. For this reason, this material was identified as "flood plain soil/sediment" and refers to materials within the approximately 1-mile wide flood plain area. The "upland" areas and the "beach" areas of the Lower Basin CUAs are in close proximity to one another. Lastly, a receptor is presumed to spend an equal amount of time in upland areas as in beach areas. It is also assumed that receptors will have an equal probability of visiting one CUA in the Lower Basin as another. As a result, the data were combined and an average concentration representing the aggregate exposure in the Lower Basin is appropriate, as specified by EPA risk assessment guidance (1989, 1992, 1996).

3d General Response Regarding Use of House Dust Data in Site-specific Analysis: *Comments were received that the dust and lead loading measurement methodology employed in the Basin was unconventional and may not represent actual exposures to children in the area. Dust lead exposures were measured by two independent techniques. Samples were collected from home* *vacuum cleaners, if these were available and had not been used outside or in the family car, and by entryway mats. The former technique measures lead concentration in the minus 175 micron fraction of vacuum cleaner dust. This method has also been continuously monitored in the BHSS since 1974 and has been a significant correlate of both blood lead and soil lead levels at the Superfund site. The second technique measures both dust lead concentration from the same size fraction, and the accumulation rate of both dust and lead on the mat. The accumulation rate of lead, or lead loading rate on these mats was the single strongest environmental source correlate with blood lead in the site-specific analysis (r=0 .63). Blood lead is also significantly correlated with interior and exterior paint lead (r=0.341 and 0.407, respectively), yard soil lead concentration (r=0.158), and community-wide soil lead concentration (r=0.116).*

Divergent opinions were offered in comments as to whether these were "poor, good or significant" correlations. The significance criteria used was the p=0.05 level. Whether the correlation coefficients are "poor or good" is a matter of opinion. A low correlation coefficient does not necessarily imply an unimportant or absent relationship. The variables may be directly related in a non-linear manner or dependent on the effect of other variables. Reviewers familiar with these types of studies have concluded that these correlations are typical and provide useful information in assessing such situations. The relatively strong and consistent correlations among these variables suggest that dust lead loading is an important factor in the environmental exposure and lead absorption situation in the Basin.

Comments were received that suggested that soil should not have been used as a surrogate for house dust concentration data for metals other than lead. These comments suggested this was inconsistent with the lead methodology and that there were sufficient data to characterize non-lead metals for house dust data in the risk assessment equations. The HHRA concluded that insufficient data were available for <u>each geographic subregion</u> because paired soil-dust data were not available for every home. The primary reason the data were not used in the risk and hazard calculations was because the uncertainty in predicting dust concentrations from soil concentrations was considered more problematic than the uncertainties of using the soil data as a surrogate. Paired soil and dust data for lead were available for over 800 homes compared to 84 homes for non-lead. As a result, actual dust data were used for lead and the soil-dust relationship for lead was reasonably well characterized and compared to results at other sites. Similar data from other sites is not available for non-lead contaminants. The HHRA acknowledged the uncertainties associated with using yard soil as a surrogate for house dust concentrations and indicated whether exposure point concentrations for various non-lead metals might be over or under estimated (see discussion on pages 7-14 through 7-16 of the HHRA). These concerns do not apply to lead risk assessment as observed dust lead concentrations were utilized.

4 Comments Related to the Quantitative Site-specific Analysis of Blood and Dust Lead Levels: There were several comments regarding the site-specific quantitative analysis relating blood lead levels to environmental variables and exposure factors. Comments disagreed regarding what constitutes "good", "high" or "significant" correlations or multi-variate regression relationships. Comments also failed to agree on the interpretation of the results. Of particular concern was the paint-soil-dust-blood lead relationship. Most comments agreed that the strongest relationship with blood lead was dust lead loading rate as indicated by the entryway mat. Because dust lead loading is, in turn, most highly correlated with yard soil lead concentrations, some reviewers see this as evidence that soils are a primary contributor to dust lead and blood lead levels. Others speculate that entryway mat lead loading reflects lead paint sources on porches, doorways and exterior surfaces. Others indicate that the influence of dust loading is indicative of home hygiene practices that are, in turn, reflective of lower socio-economic status and associated personal and family hygiene practices. Other reviewers suggest that entryway mat lead levels are not indicative of lead levels within the home. Several reviewers pointed out that the robustness of paint lead blood lead correlation is decreased or eliminated by inclusion of community mean soil lead levels in step-wise regression analysis. Some comments interpret this to mean that older communities have higher soil lead levels due to the long mineral industry history and, coincidentally, more lead paint due to the age of the housing. As a result, the significance of paint lead diminishes after accounting for community-wide soil lead. Others conclude that the higher community soil lead levels are related to deterioration of the exterior paint. Some comments suggest deleting homes and blood lead observations with known or suspected paint lead exposures from the analysis.

4a General Response Regarding the Quantitative Site-specific Analysis: *These relationships were assessed using multi-variate analysis in Section 6.4.2 of the HHRA. With respect to blood lead levels, backward selection step-wise regression analysis indicated that dust lead loading rate alone explained nearly 40% of the variance in the dependent variable. Other environmental variables were significant in combination with dust lead loading rate. Those variables were yard soil lead levels, median exterior paint XRF reading, and interior paint condition. Together with age of the child, these variables explain 60% of the variance in blood lead levels. It is well established in the lead health literature that there is an inherent variance in blood lead response among individuals in a population. Considering that this regression model does not address this inherent variance, accounting for 60% of the variation in observed blood lead levels must be considered a strong relationship. The interpretation of these results in the HHRA was that contaminated soils, house dust, and lead based paint are all related to excess absorption. Overall this suggests complex exposure pathways, with blood lead levels most related to dust lead loading in the home, followed by independent effects of yard soil lead, interior paint lead condition, and exterior paint lead content. The dust lead pathway is most influenced by outdoor soils, augmented by paint contributions in older homes, especially those in poor condition.*

Differing interpretations were offered by reviewers. Few comments addressed the blood lead environmental exposure model. Most comments addressed the model explaining dust lead loading rate. Multi-variate regression analysis using dust lead loading rate as the dependent variable indicated four significant variables including yard soil lead concentration, interior paint condition, the maximum interior lead paint XRF reading in the home, and the mean soil concentration in the local community. The dust lead loading rate is calculated by multiplying the *total dust accumulation rate by the lead content of that dust. Results of step-wise regression analysis, also shown in Section 6.4.2 show that dust lead content on these mats is most related to yard soil lead concentration followed by interior paint lead condition. The next most significant variable by backwards elimination is the community mean soil lead level at the p=0.0001 level. No other variables are significant at the p=0.1 level in the presence of these factors. If community mean soil concentration is eliminated from the selection, the maximum interior paint lead XRF reading and the exterior median paint lead XRF reading are significant at the p=0.02 and 0.03 level, respectively. Vacuum bag lead concentration is related to the mat lead concentration (p=0.001), yard soil concentration (p=0.01), and maximum interior paint lead XRF reading (p=0.03). Vacuum bag lead content typically exhibits about a 30% to 40% lower concentration than mat lead content. Some comments speculate that the elevated mat lead concentrations are due to paint lead contributions from the entryway areas and are not reflective of dust lead exposures to children. The significance of the paint lead variables in the mat dust lead concentration model is suggestive of this effect. However, the non-significance of these variables in the presence of the mean community soil lead concentration, could imply that these effects are related to community-wide lead levels that could, in turn, be a surrogate for the age of the community. Those towns showing the highest soil and dust lead levels also have the oldest housing stock, highest lead paint levels, and longest history of industrial pollution.*

Suggestions were made regarding the inclusion of socio-economic variables and development of lead-paint condition interactive factors or cross products in these analyses. However, as was noted for the proposed socio-economic characterization of the blood lead data set, insufficient data are available to perform these adjustments. Suggestions were also made to perform separate analysis of homes with and without paint hazards. This analysis would also be difficult as most homes, other than trailer homes, have lead paint. The primary indicator of paint condition (peeling/chipping/chalking paint) has been shown in the parent 1996 Basin Exposure Study to be highly correlated with home hygiene and socio-economic status. As a result, it is not clear whether the significance of this variable is reflective of the paint source of lead, socio-economic status, personal and family behavior, home hygiene practices, or dust loading.

In summary, several comments have offered additional speculation regarding the interpretation of site-specific analysis. Most comments agree that house dust lead loading is strongly correlated with blood lead levels. Comments do not agree with respect to the source of lead on these mats. Some believe the evidence is supportive of paint lead sources, others believe outdoor soils from both the yard and community are primary sources. The HHRA concluded that both sources are likely significant, but there is uncertainty regarding paint sources due to the relationship between paint condition and socio-economic status that cannot be unraveled with these data. That conclusion remains unchanged. These findings are consistent with the follow-up reports from public health nurses investigating children with high blood lead levels and results from other sites including the nearby BHSS. As a result, risk managers should consider both sources potentially important to lead poisoning in the Basin.

5 Comments Related to Incremental Exposures: A number of comments were received regarding incremental exposures. Some of these comments noted that the presentation of incremental exposures was confusing and that some of the descriptive terminology was ambiguous. Many of the comments were contradictory. Some comments indicated that it was inappropriate to combine various incremental pathways, as it is unlikely that any individual would engage in all these behaviors. Similar comments objected to double counting of exposures or the failure to discount residential exposure from the typical baseline intake for children recreating outside the home environment. Other comments indicated that this approach resulted in multiplying various conservative assumptions and safety factors, resulting in unrealistic scenarios and over-stating risk. Others, conversely, noted that the document fails to indicate that all of these pathways could be active for some individuals. Similar comments objected to assuming average or typical baseline residential exposures for those children that might engage in the recreational activities. These comments argue that the children with high intake rates at home are more likely to have high intake rates during recreational activities, that risks are understated, and that no margin of safety is provided in the analysis for these children. Comments were also received indicating that mixed age bands were applied in the analysis in that some young children are unlikely to engage in certain activities. Several comments objected to the averaging periods employed for the various behaviors and the allocation of those intakes over an annual period in the application of the IEUBK model. Comments objected to applying RME parameters to lead analysis indicating that the IEUBK analysis inherently accounts for high exposure rates. Others objected to the use of the IEUBK model to assess periodic or episodic behaviors, citing EPA policy statements. These comments indicated that the averaging times used overstate risk, and that longer averaging periods should be utilized. EPA's Technical Review Workgroup for lead (TRW), that reviewed the document, conversely indicated that the model is applicable, that shorter averaging periods should be used, and the document likely understates risk. Some comments were received regarding the inappropriateness of certain assumptions used in the intake estimates. Comments objected to contact rates at waste rock piles, as these areas have little exposed fines, and the use of disturbed water samples, those with significant levels of suspended sediment, to represent beach activities. Several comments were received regarding the Rails-to-Trails conversion of the existing railroad right-of-way through the Basin. Comments were submitted that the HHRA failed to consider potential exposures associated with the trail, that the trail would invite people into contaminated areas, that the risk management plan adopted for the trail in earlier EE/CA actions was insufficient, that contamination in areas outside those geographic areas considered in the HHRA were ignored, that demographics and private property throughout the Basin were not adequately addressed in the HHRA, and that wastes in the Lower Basin were miscategorized as to source and description.

5a General Response regarding the Characterization of Incremental Exposures: *Incremental exposures are introduced in Section 6.5.3 of the HHRA as estimated lead intake rates. Incremental lead intake rates refer to the amount of lead taken into the body during activities in which only certain members of the population engage. These individuals either consume more soil, dust, water, or food than the general population, or those media have higher lead content. Incremental intake rates were developed both for the typical (Central Tendency (CT)) and* *reasonable maximum exposure (RME) members of the population. Estimating the intake rates is a relatively straight-forward procedure utilizing exposure factors developed elsewhere in the document. Generally, these factors are linear and intake estimates are proportional to exposure point concentrations, contact times, and exposure frequencies. Should risk managers disagree with the underlying assumptions or wish to consider alternative factors, the incremental intake rates can be adjusted accordingly. This option is discussed in more detail in General Response to Comment # 7b.*

Estimation of potential blood lead increments and the increased risk of exceeding critical toxicity levels associated with these intakes, however, presents additional challenges. Incremental exposures should be evaluated as a cumulative effect added to exposures received in the home environment. This is accomplished by adding the incremental intake of lead to the baseline (or residential) intake. There is a significant question as to characterizing the baseline exposure to which the increments should be added. Should the baseline reflect the typical child residing in the Basin, a child from outside the Basin, or the child most at risk within the Basin? Should this analysis be performed for current conditions, or for projected post-remedial lead levels, following cleanup in the residential areas? There is a question as to whether the baseline should be discounted to avoid double-counting intake during incremental activities (i.e., the child is not at home when at the beach). However, most children do not engage in these behaviors and discounting the population baseline would underestimate their risk. Other questions are related to combining incremental behaviors. All children will not engage in all incremental activities, but some children will engage in one or more activity, and a few might engage in all the activities considered. Which combinations of potential incremental intakes should be assessed? Other concerns are related to application of the IEUBK model to incremental exposures. In the IEUBK model, mean blood lead estimates are developed for typical children assuming a uniform annual exposure. RME characterizations are estimated by applying a distribution of responses around the mean. Because various members of the population will have different exposures, depending on which incremental behaviors they engage in, estimates of the number of children to exceed critical toxicity levels are difficult to interpret.

There are concerns related to averaging periods for the incremental exposures. Should the incremental intake be averaged over the period of exposure, the season, or the year? How should these average intakes be input to the IEUBK model? The IEUBK is not designed to address episodic behaviors, but near equilibrium responses are achieved in a few months and the model has been successfully used to assess seasonal inputs. The EPA's Technical Review Workgroup (TRW) recommends using 2 to 3 month averaging periods for these applications. The TRW concludes that the exposure duration is sufficient to include in IEUBK analysis, but believes the risk may be understated, by about 35%, as the exposure should be averaged over the seasonal exposure duration rather than the 365 day year. Additionally, the recreational ingestion rates are applied only for those hours in the day during which the activity occurs, although the rates used could be considered event related. For example, the 300 mg/day RME soil ingestion rate for upland parks is applied for 7 hours/day, or 50% of waking hours, resulting in 150 mg of soil ingested while recreating. An alternative interpretation of the ingestion rate would be 300 *mg/day per even , resulting in doubling the recreational soil intake. As a result, risk managers may want to consider risk potentially underestimated for incremental behaviors.*

Finally, the concept of RME is problematic with these exposures. Extreme responses in the population can be estimated by applying an appropriate GSD to the mean blood lead estimate from the IEUBK model, although this is difficult to interpret as noted. This technique requires that typical, or CT intake rates be input to the model for both the baseline and incremental exposure. The extreme responses estimated by applying the GSD reflect the biokinetic variation in the population and the variation inherent in the typical exposure. However, there are environmental extremes in the potential incremental exposures to consider in addition to the bio-kinetic response and typical baseline exposure factors. Some children, for example, may always play at the most contaminated beaches, rather than at the typical or average concentration. The RME scenarios used in the IEUBK reflect CT ingestion rates for both the baseline and incremental exposure applied at 95th percentile contact concentration.

5b General Response regarding the Approach to Quantifying Incremental Exposures: *Comments received addressing several of these questions were variously characterized as overestimating or underestimating risk, depending on the understanding and perspective of the reviewer. The IEUBK model, if appropriately applied, is capable of estimating risk and providing useful information to risk managers for nearly all of the situations noted above. However, the application of the model must be precisely described and interpretation of the results limited to the particular situation evaluated. For example, assessing the incremental risk for a child visiting a contaminated recreational area on a seasonal basis requires identifying the baseline situation from which the child originates, the estimated incremental intake from the recreational activity, and the estimated intake from any other incremental behaviors. Determining these intakes requires specifying where the children live, and where and for how long they engage in these activities. The intake estimates must then be reconciled to a common exposure period, or averaged over either the seasonal exposure period of the incremental activity or the annual baseline exposure period. The IEUBK model is then run for both the baseline situation and the combined baseline and incremental behavior. This can be accomplished either by developing a time-weighted intake average incorporating both the baseline and incremental behaviors, or by inputting the incremental intake as an additional source. The results can then be compared and the blood lead increment interpreted as the increase predicted for the typical child exposed to this particular situation. The difference in the predicted percentage of children to exceed 10 ug/dl would be the interpreted as the increased probability that an individual child from that baseline situation would have an excessive blood lead level as a result of the incremental behavior(s).*

These results would apply only to those children from that particular residential area engaging in those particular activities, or similar communities and activities. However, there are hundreds of possible combinations of baseline and incremental exposure situations that could be of interest in the Basin. Assessing each situation individually would require a substantial effort to accomplish and would produce a large amount of results to interpret, much of which would be *superfluous to risk management considerations and decision-making. As a result, the HHRA assessed a limited number of scenarios under current baseline conditions and introduced a methodology by which other scenarios could be evaluated during risk management activities.*

In the HHRA, incremental lead intake rates were determined for a variety of potential activities that could significantly add to the amount of lead taken into the body. These rates were developed on an activity specific basis for both a typical (CT) or a worst case (RME) estimate. Initial soil, dust, food, and water ingestion and inhalation values used for these intake calculations correspond to those developed for the non-lead risk assessment. These intake rates are compared to baseline intake in Section 6.5. Risk managers can assess the incremental and total intake, and compare the relative increase. In Section 6.6 those intakes are input to the community mode IEUBK model as an additional source. The community mode was selected because the mean blood lead and percent to exceed estimates represent the most likely value for the typical child in each community. This estimate is most representative of the overall exposure situation for each community, as the batch mode data set is limited to those individuals for which blood lead levels are available. The community mode also facilitates the estimate of the percent of children to exceed specified toxicity levels. The resulting mean blood lead estimate from this procedure should be interpreted as the estimated blood lead level for the typical child from each community that engaged in the selected incremental activity. The percent to exceed estimate should be interpreted as the likelihood that the typical child will exhibit an unacceptably high blood lead level. These results are compared to the baseline estimates without the incremental exposure and the difference can be attributed to the incremental activity.

5c General Response regarding the Combined Baseline and Incremental Exposures:
Reviewers and those using these estimates must consider several of the concerns noted above. The baseline estimates included in the combined runs are not discounted for the time spent in the incremental behavior. This leads to an overestimation of risk, albeit small for the current baseline situation. For a child, about 5% of the baseline intake would be double counted at typical soil concentrations. However, as noted below, accounting for this reduction in baseline in the post-remedial environment will be important. In the HHRA, the incremental intakes are averaged over the year to correspond with the exposure period inherent in the residential baseline exposure estimate. This results in a probable underestimation of risk, in that blood lead levels reflect the annual average, whereas it is likely that blood lead levels will be higher during the exposure season.

It is also important to note that the estimated blood lead increment is dependent on the baseline blood lead level. As a result, because these estimates are developed at the current baseline that is unacceptably high, the same incremental intake applied to an acceptable, lower post-remedial blood lead level will result in a larger blood lead increment. This is because the dose-response relationship is non-linear and the intake at lower baseline blood lead levels will result in a greater response. The probability of exceeding the 10 ug/dl toxicity threshold then depends on both the baseline blood lead level and the increment. At acceptable post-remediation blood lead levels, the accounting for time away from the baseline for incremental activities becomes critical.

If there is no margin of safety incorporated in the residential baseline exposure, then the incremental intakes must not exceed the reduction in baseline intake due to the time away from home engaging in the incremental behavior.

For this reason, no post-remedial examples of potential cleanup criteria were provided for risk assessors as was accomplished in Section 6.7 for the residential or baseline situation. The examples provided should be reviewed as indicators of whether these activities result in substantial or significant increases in intake or blood lead estimates. However, using these results to effect remedial strategies must be done with caution. Potential cleanup estimates would not be relevant until risk managers suggest or provide criteria for residential exposure reductions. Should risk managers select a minimal residential cleanup criteria, (i.e., the highest allowable intake rates and corresponding soil and dust lead concentrations), then the corresponding criteria for incremental exposures would be that which results in offsetting the post-remedial residential intake during the time away from home engaging in the incremental activity. This result could be calculated without employing the IEUBK, requiring only a net balance of lead intake be achieved. These calculations could also include other considerations, such as local input regarding adjustment of exposure factors, consideration of age-specific responses, and institutional or intervention techniques that could reduce ingestion rates. If however, risk managers elect to provide some margin of safety in the residential criteria, then higher intake rates could be considered for recreational activities and higher criteria could be developed and assessed through the use of the IEUBK.

Risk assessment for the non-lead metals did not add risks from different receptor groups (i.e., residential with public recreational) but additional sources of exposure were expressed as potential incremental risks above the residential baseline and the possibility of "double counting" was noted. Because of the many sources of metals exposures possible for individuals in the Basin, the added health risks from certain activities outside the home should be acknowledged so that appropriate risk management decisions can be made on a location-specific basis. There is an example of the residential and neighborhood recreational scenarios combined in Section 5 in a qualified manner. This analysis was provided primarily to illustrate the potential for additional exposures outside the home, and to demonstrate that risks could increase over baseline residential risks if residents also engage in recreational activities.

5d General Response regarding Incremental Exposures associated with Rails-to-Trails:
Consideration of potential recreational and occupational exposures associated with the Rails-to-Trails conversion are subsumed under the recreational and occupational scenarios considered in the HHRA. The types of activities anticipated for trail users and workers are accounted for in the scenarios addressed in the HHRA. Those include upland park activities, public beach activities, neighborhood sediment activities and nominal recreational activities associated with the residential scenario. The HHRA recognizes that public beaches and other common use areas throughout the Basin, including railroad right-of-way, are routinely used by members of the public. That was one criteria for sampling these areas for HHRA assessment. Incidents of excess lead absorption have been attributed to common use areas in the Lower Basin. There are

numerous public access areas throughout the Basin that will be assessed in the development of a Proposed Plan for cleanup. This effort will include properties on, adjacent to, and remote from the railroad right-of-way. All of these properties can be evaluated by the same methodology provided in the HHRA, and described above. Incremental exposures were characterized using typical parameters that are specified in the HHRA. Intakes are calculated in a straight-forward manner proportional to those parameters and media contaminant concentrations. Should risk managers elect to modify these parameters to site-specific concerns, intake rates can be adjusted proportionately. Blood lead increments can then be estimated by IEUBK applications or intake offset calculations can be performed to determine appropriate cleanup criteria. These calculations can be performed for sites on or off the right-of-way. The HHRA is familiar with the risk management plan adopted for the trail. That plan addresses the areas likely to be accessed on the railroad right-of-way. Within 1000 feet of any residence the entire right-of-way will be provided with a clean surface. This addresses the nominal aspects of recreation associated with the residential scenario. At all major access points, sidings, and select oasis location, similar right-of-way cleanup will occur and large oases are strategically placed along the trail to provide clean rest and stop-and-view areas. In remote contaminated areas warning signs will be posted to alert trail users to areas presenting excessive risk similar to warnings to avoid local hazards in numerous venues. The signage is provided to both advise users to avoid undesirable areas and to identify safe areas to recreate. The proposal was extensively reviewed by a number of public agencies and governments including the EPA, Panhandle Health District, State of Idaho, Coeur d'Alene Nation, several federal trustee agencies, and the Agency for Toxic Substance and Disease Registry. All have found the risk management and cleanup plan to be compliant with pertinent rules and regulations and protective of public health.

6 Comments Related to Subsistence Exposures: Contradictory responses were also received with respect to exposure estimates associated with Native American subsistence activities. Some comments suggested that inclusion of subsistence scenarios was inappropriate as these are largely hypothetical lifestyles that don't currently exist and are unlikely to occur in the future. Comments noted that foodstuff contamination data submitted by tribal representatives did not include collection and analytical methodologies. Other comments indicated that high-end or excessive intake assumptions were employed regarding aboriginal activities, and that combination of these activities resulted in highly unlikely estimates. Other comments suggest that the HHRA is not comprehensive with respect to subsistence scenarios in several regards. These reviewers believe that the geographic areas evaluated were based on arbitrary political boundaries that distort the risk assessment. These comments note that most of the Coeur d'Alene Lake and Spokane River in Idaho was screened out of the HHRA based on preliminary studies. The comments note that these studies concluded in Idaho that no further data collection was warranted, while health officials in Washington State concluded that fish in the Spokane River present an unacceptable risk. These reviewers believe that the screening assessment was flawed because assumptions protective of subsistence pathways were not included in the screening and that the Preliminary Remediation Goals (PRGs) used for comparison were ill-conceived with respect to subsistence requirements. The comments also note that dioxins, PCBs, herbicides, poly-aromatic hydrocarbons and other contaminants potentially significant to subsistence pathways were not addressed. These comments also note that several media of potential significance were also not addressed including crustaceans, amphibians, mollusks, natural building materials used in lodge construction, mosses, herbs, ash, bark, and plant material used in clothing, medicines, and ceremonial practices. As a result, these comments conclude that the HHRA was not comprehensive with respect to potential subsistence pathways and underestimates risk. Other comments suggested that those exposure factors derived from literature values attributed to Tribes near the Hanford Nuclear Reservation were inappropriate to the Coeur d'Alene Tribe in the Basin environment.

6a General Response regarding Subsistence Exposures: *Subsistence scenarios and relevant exposure factors were developed in cooperation with Coeur d'Alene Tribe representatives. The Traditional and Current Subsistence scenarios were requested by the Tribe as representing possible future uses of the area. Exposure factors were derived specifically for the Coeur d'Alene Tribe. Scenarios and exposure factor analysis were patterned after the development of similar scenarios for the Columbia River Tribes. A cultural anthropologist, working for the Coeur d'Alene Tribe, reviewed and suggested appropriate modifications for each of the exposure factors. Each pathway was characterized individually. Risk managers can combine pathway results as considered appropriate to estimate total intake rates. However, it should be remembered, as noted in the HHRA, that intake from dietary sources may be more highly absorbed than those from soil and sediment sources. Numerous potential pathways and contaminants were not addressed due to lack of data. These pathways are discussed in Section 3.2. Little data exist for organic contaminants. The HHRA addresses the geographic area extending from Harrison to Mullan. The area of investigation was determined jointly by the EPA, State and Coeur d'Alene Tribe. The results and conclusions of the HHRA should not be extended to Coeur d'Alene Lake or the Spokane River except as explicitly noted.*

With respect to recreational, occupational and residential exposures to the resident population, most of Coeur d'Alene Lake and Spokane River areas were excluded based on the earlier screening risk assessment. However, neither screening risk assessment addressed high levels of exposure associated with subsistence lifestyles. The HHRA concluded that achieving appropriate levels of risk for subsistence lifestyles would require levels of environmental contamination comparable to background concentrations (Executive Summary and Sections 6.7.6 and 8.2.6). Although concentrations of metals surrounding Coeur d'Alene Lake occurred below screening levels, risks for subsistence lifestyles may remain unacceptable. With regard to the upper Spokane River, the Washington Department of Health recommended against consumption of whole fish. Beaches sampled along the Spokane River located downstream from the Upriver Dam were found to have metals concentrations comparable to naturally occurring background levels. Sample results in the upper Spokane river were also near background. Samples collected by the EPA and USGS showed decreasing metals concentrations from east to west along the Spokane River.

Harrison beach and Blackwell Island were retained for additional consideration in the HHRA. A determination was made that insufficient data were available to assess sport or subsistence *fishing in Coeur d'Alene Lake and downstream tributaries in Idaho. No evaluation of subsistence lifestyles, including the screening level risk assessment, has been accomplished for Coeur d'Alene Lake or Spokane River areas.*

7 Comments Related to Site-specific Exposure Parameters: Comments were received regarding the use of ingestion and frequency of contact assumptions for soil sources that were developed from guidance and reviews of studies and literature from locations outside the Silver Valley. Some comments suggested that these parameters should be adjusted to reflect the comments of local respondents to questionnaires circulated prior to development of the HHRA. Many of these comments pointed out that soil contact was seasonally dependent due to snow cover in the winter, that many of the potential recreational and waste pile sites included in these surveys were little used or unknown to locals, that many of the sites listed in the HHRA were waste rock piles with little accessible fine material, and were unattractive as recreational areas. Other comments suggested that "high-end" ingestion estimates were used for several potential intake rates. Some comments also addressed a perceived lack of definition of exposure areas.

7a General Response regarding Site-specific Exposure Area Parameters: *Typically, risk assessment is designed to over-estimate, rather than under-estimate health risks in order to make appropriate risk management decisions that err on the side of protecting public health. The estimates used in the risk calculations for neighborhood and public receptors are weighted upwards in part to protect the very high frequency outdoor exposure of some children. Some comments suggest that the exposure frequencies and duration likely overestimate exposure for recreational receptors. Exposure frequency times used in the recreational scenarios, in terms of hours per day, are recommendations from EPA's 1997 Exposure Factors Handbook containing national information. Children in the more rural areas of the Basin would not be expected to spend less time outside than times estimated from the national information that includes urban children. Information from the Panhandle Health District's (PHD) lead intervention program does indicate that many children do spend very large amounts of time outdoors, particularly in summer (12 hours a day for some children).*

Exposure to soil both by ingestion and dermal contact continues during the winter inside the home, although likely at a reduced rate, because soil continues to be a component of indoor dust in the winter. It is reasonable to expect that some reduction in exposure to soil-borne contaminants may occur during times of snow cover. However, exposure attributable to soil continues as snow cover is not impervious to contaminated soils, snow cover may become contaminated with soil contaminants, winter footwear may enhance soil tracking into the home, snow may create muddy conditions that increase tracking of soils, and children have increased exposure to interior dusts during the winter. Rather than adjusting soil rates downward and dust rates upward in the winter months, both the soil and house dust components of "dirt" ingestion are averaged for the year in lead risk assessment . For non-lead exposures the RME scenario did not adjust contact downward for winter while the CT scenario assumed no contact. These two assumptions potentially bound the actual amounts ingested/absorbed. Data from waste rock piles were evaluated only for the populations of Mullan, Nine Mile, and Canyon Creeks. The *waste pile data included in the HHRA were collected from piles near residential homes. Data from piles were evaluated separately, and the data were not mixed with other media. The fine material in waste piles is present in the top inch and this material would adhere to children's hands and be ingested; however an insufficient amount was present for laboratory analysis. Samplers collected material to a depth of 6 inches. The assumption is that the concentration found in the 0-6 inch depth is representative of the concentration in the top inch.*

The HHRA agrees with comments that the dermal surface areas used for the 4 to 11 year old age group were excessive for the exposure period. Preliminary estimates indicate neighborhood risks and hazards will decrease by less than 10% if skin surface areas are reduced. Risks and hazards for combined neighborhood exposures are not risk drivers and dermal exposures were a relatively low percentage of the total neighborhood risks (35% to 17% for arsenic). Modifying skin surface areas for neighborhood exposures does not affect the conclusions of the risk assessment or potential risk management strategies. Table 3 summarizes the change in risk and hazard estimates if reduced skin surface areas are used in the calculations.

With regard to exposure area definitions, the Coeur d'Alene Basin is an extremely large and complex area. Early in the planning process, in order to meet public requests, the HHRA was placed on an accelerated schedule to be completed in parallel with the RI/FS. It was recognized that, with the associated time and budget constraints, sampling efforts would be limited. Decisions were made to utilize existing data to the maximum extent practicable, fill major data gaps with focused sampling efforts, and not address all possible data gaps and exposure pathways. As a result, the data organization effort used the Idaho Department of Health and Welfare and Panhandle Health District lead health investigation and databases to define exposure areas for residential risk assessment. The HHRA relied on the Conceptual Site Model (CSM) approach of the RI/FS to incorporate efforts from federal environmental and ecological studies. The HHRA acknowledges that human exposures would only occur in a portion of the large CSM "exposure areas" identified on the maps in Section 3 and would focus on population centers. In general, the majority of the data used in the HHRA was at or near a home and/or population center and does represent reasonable human exposure potential (see Figures 3-12 through 3-26 in Section 3 for non-residential sample locations). Neighborhood exposures for elementary-aged school children are likely limited to areas reasonably close to home and in general, the sample locations used to evaluate neighborhood exposures are close to at least a few residences. Because much of the population is decentralized and the Basin is very large, a potential play area close to one home will be far from another within the same geographical region. The HHRA elected to address this complexity by determining average exposures to sediments, surface water, and waste piles in potential play areas within a region and evaluate whether such behavior might be "risky". Risk management decisions will be on a site-by-site basis and will likely require additional sampling and consideration of site-specific use patterns and proximity to residences.

7b General Response regarding Use of Public Input in Developing Site-specific Exposure Parameters: *A summary of the public comments received during the development of the HHRA* *will be included in the Appendices to the final document . Substantial efforts were made in the HHRA to address the concerns and input from the local citizens. Many comments were submitted regarding the applicability of the exposure factors developed and assumptions made to the Silver Valley. Comments provided indicate that residents are concerned that these factors were developed at other sites with conditions that do not apply to their town. The HHRA addresses these concerns by relying to the extent possible on observed blood lead levels from the Basin. The follow-up results from the Panhandle Health District's investigations of lead poisoned children were carefully examined and reviewed. The site-specific analysis was conducted to examine the relationships between observed blood lead levels and environmental exposures. The lessons learned at the Bunker Hill Superfund Site (BHSS) were applied to the extent possible. In particular, IEUBK modeling results have been carried out by both the EPA Default model that is generically applied to sites and the Box Model used at the BHSS and the results of both models are compared to observed blood lead levels in the Basin. All residential, recreational and occupational exposure factors utilized are appropriate to northern temperate climates.*

Several comments refer to poor people or socio-economically disadvantaged families that possibly make up a disproportionate number of children with high lead blood lead levels. Others indicated that other sources of lead, aside from the mining industry, may be responsible for the high levels. In response, the HHRA provides a detailed description of Basin demographics, poverty levels and indicators, and discussions of the relationships between poverty and lead poisoning. The HHRA does address lead paint and the relationship between lead in blood, soil, paint, and dust in detail.

Many comments were received regarding distrust of the federal EPA, the desire to not be listed as a Superfund site, to let the State implement and manage the cleanup, accomplish the fastest possible cleanup, or not to have any cleanup. In response, the HHRA provides and contrasts current EPA policy, the federal Centers for Disease Control (CDC) guidance on lead poisoning in children, and the Remedial Action Objectives (RAOs) that have been employed at the BHSS. The HHRA also discusses, to the extent practicable, potential risk management tools and potential cleanup limits, as a vehicle to facilitate addressing these items in the overall process.

There were several comments regarding the use and obscurity of the various Common Use Areas (CUAs) listed in the survey. Many respondents said that they had lived in the Basin for their entire lives and either didn't know of these areas as recreational sites or never knew of anyone to use the site for recreation. In response, the HHRA developed intake rates for these sites as incremental exposures based on assumed frequencies. In this way the impacts of these sites can be assessed in addition to (or incrementally) to other sources of lead. Should risk managers believe that less time is spent at these areas, the increment can be adjusted proportionately. In this manner each site can be evaluated individually, should risk managers or the public deem that appropriate.

There were numerous requests from the public asking that they not be lectured to, that they be provided with the details of the assumptions being made, but that too many technical terms were *being used. Some feel they are not being provided with appropriate details and uncertainties with the assumptions made, etc. Others want the bottom line in plain language. These frustrations seemed to indicate that different levels of communication will be required to effectively inform the public about these issues. In response, the HHRA was produced with three levels of summary, a lengthy uncertainty discussion, and an immense Appendix with numerous details and support information. The document itself contains many figures and tables to illustrate the main points with a significant level of detail. Each section is individually summarized. Much of these summaries is repeated in the Section 8 Summary and Conclusions, that was circulated as a stand alone document for general public review. There is also an Executive Summary that provided the highlights of the HHRA for those wishing the shortest version. For those interested in complete detail, a 1400 page Appendices was provided on CD. Section 7 of the document is a lengthy discussion of the many uncertainties associated with a project of this type. As a result, the HHRA is repetitive, but provided a level of detail appropriate to the various audiences.*

8 Comments Related to Exposure Pathways: Several comments referred to pathway considerations. Some comments indicated that lead paint-related pathways were over-emphasized in both graphics and in the analysis. Others felt that paint lead exposure was under-represented and the document was biased toward soil as the primary source of lead to children in the Basin. Comments were received indicating that secondary sources of lead to the home, such as soil tracked into the home from construction workers, those employed in the minerals processing industries, and older children and adult's recreational activities were ignored. Some comments indicated that the effects of soil on blood lead levels were understated, as the document ignored the soil-to-house dust-to-blood lead pathway. These comments suggested that blood lead impacts attributed to dust, are, in fact due to soil, manifested through dust. Others argued that the same effects were, in turn, due to deteriorating paint. There were also contradictory comments regarding the contribution of dietary lead to observed blood lead levels. Comments were received noting that dietary lead is absorbed at a higher rate than lead from soil and dusts. Other comments suggested that recent work by Manton et al. suggests that dietary lead plays a minor role in contemporary lead exposure, and that blood lead reductions noted in the 1990s were due to reduction in dietary lead throughout the U.S. One comment objected to the presentation of a single age-group in the section of the document illustrating relative contributions to estimated total lead intake from different pathways.

8a General Response regarding Exposure Pathways: *Most of the comments received regarding pathways suggested alternative interpretations of the results of the site-specific and IEUBK analysis. These comments, for the most part, indicated that various pathways should be emphasized to a greater or lesser extent. General Responses 3a-d and 9a-d discuss the site-specific and IEUBK analysis, respectively. Many of the pathways-related comments address dust and speculate on the various sources of lead to house dust. It is important to note that actual observed house dust lead levels were used in both the site-specific and IEUBK model analysis that relate blood lead levels as a dependent variable to environmental dust concentrations. Except in the IEUBK application, where mean community dust lead* *concentrations were substituted for missing observations, these were paired observations from individual homes. As a result, the sources of lead to dust, such as paint, yard soils, materials tracked in by workers, fugitive dusts, etc. are inherent in the analysis. Dependent blood lead levels are directly related to house dust and other environmental sources as independent variables in either the empirical or mechanistic model derived analysis.*

In either case, house dust is identified as the largest source of lead, particularly to young children. Any significant effects in addition to dust from soil or paint are similarly independent and likely represent primary source pathways exclusive of house dust. However, outdoor soils from the home yard and neighborhood, deteriorating paint, occupational or recreational contaminants on clothes and shoes, windblown dusts, and others are potential sources of lead to dust. In this sense, dust is a secondary source of lead to children, the lead ultimately coming from the other sources. It is important to quantify these effects in order to develop remedial strategies that will reduce dust lead concentrations. These soil and paint-to-dust-to-blood relationships can be evaluated simultaneously through pathways, or structural equations analysis, as some comments suggest. This was accomplished for the BHSS, using an accumulated data set of several thousand observations collected over a decade. There were insufficient data available to undertake structural equations analysis for the Basin data set. As a result, blood lead and dust lead were evaluated as dependent variables in separate regression models. These results were discussed in General Response to Comment # 3. The findings showed little difference from the same models applied to the BHSS data set, as discussed in General Response to Comment # 4e. The same source variables were significant and the regression coefficients or slope values were similar.

As a result, the findings regarding pathways explored through structural equations analysis at the BHSS are useful to consider in relation to the comments offered for the HHRA. These models indicate that about 40% of the blood lead absorbed from soils and dusts is through house dust with about 30% from community-wide soils and 30% from the home yard and immediate neighborhood. These relative contributions agree with findings of earlier studies conducted in the early 1980s and analysis used to develop the cleanup criteria for the BHSS. The same structural equation models suggest that community-wide soils contribute between 50% and 60% of the soil lead component in house dust with the neighborhood and home yard contributing about 20% each. This results in soils overall contributing about 80% of lead to house dust in the pre-remedial environment and an estimated 50% to 60% post-remedial, the remainder coming from other sources including lead paint.

Analysis of the relationship between house dust and soil lead levels show that dust lead concentrations demonstrate large variation. Soil lead levels are significantly correlated with (p=0.0001), but explain only 20% of the variability in house dust lead concentration. Approximately half the soil contribution to lead in house dust is attributable to the greater community, with the remainder coming about equally from the home yard and the immediate neighborhood of the home. Review and analysis of dusts collected from mats placed in BHSS homes and associated questionnaire data, show that much of the variation in house dust lead *levels is associated with housing, socio-economic, behavioral, family and occupational and recreational related factors. Although several of these factors do not affect dust lead concentration, as much as 25%-30% of the variability in dust and lead loading rates is explained by these factors.*

Socio-economic status plays a complex role in dust loading relationships. Home or housing related factors (home age, yard covering, inside and outside paint condition); socio-economic factors (own/rent, occupancy time, number of residents); personal habit or behavior factors (use of mats, children's outside play frequency, general household hygiene, pets), and occupational/hobby related factors (mill worker, carpenter, landscaper, sanding within the home) influence dust loading rate or the amount of dust in the home. These variables are indices of complex social structure with many inter-related factors that influence both dust and lead loading in this community. In the presence of active sources of lead (i.e., contaminated soils or paint), this can result in higher dust lead loading rates. Many of the factors relate to both lead sources and dust loading. Paint condition can influence both dust and lead loading rates as a contaminant source and as an indicator of household hygiene and socio-economic status. Grass cover of the yard and general household hygiene are significant factors in that both contain lead sources and affect dustiness.

The relationships are complicated and often not straightforward. Older, more established homes may have higher lead paint content, but tend to have better paint condition and yard cover. The number of children and regular visitors and time spent outside positively correlate with owner/renter and length of occupancy status, and dust loading rate. Comparable background house dust studies were conducted in socio-economically similar communities to those in the BHSS. These communities located in northern Idaho were remote from the mineral processing industry and were selected to represent similar housing conditions. Background results suggest that concentrations in similar socio-economic and housing conditions are near 200 mg/kg lead.

9 Comments Related to the Applicability of the IEUBK "Box" and EPA Default Models: Several comments were received regarding the applicability of these models to the Basin situation and the use of the IEUBK in risk assessment and risk management activities. Comments from some reviewers indicated that IEUBK is generic and simplistic and is inappropriate for risk assessment uses in the Basin. Reviewers also offered suggestions for alternative models that they believed to be more appropriate. Other reviewers supported the use of the IEUBK, but felt the EPA Default Model was the most appropriate to apply in evaluating risk in the Basin. These reviewers felt there was insufficient evidence to justify applying the Box Model outside of the Bunker Hill Superfund Site and believed that any cleanup predicated on the results of the Box Model would not be protective of children "in the tail of the EPA Default Model". Other reviewers indicated that the EPA Default Model clearly overestimated risk in the Basin. Other comments questioned the applicability of site-specific information and the results of site-specific analysis being incorporated into the model. Comments received suggested that inclusion of such data would result in a cleanup that was not protective, others suggested that it would result in unnecessarily over-protective cleanup. Other comments indicated the IEUBK analysis was appropriate and, in combination with the thorough discussions of uncertainties, added to the base of knowledge necessary to make sound risk management decisions. Several specific technical comments addressed the use of the 18% bioavailability absorption rate in the Box Model, the inclusion of soil lead estimates from outside the home environment in the Box Model, the selection of the geometric standard deviation (GSD) in both models, and the comparison of model results to observed blood lead levels in the Basin. Comments were made both supporting and discounting the selections applied for these factors in the HHRA. Other comments noted the differences in model performance among the geographic areas, some indicating that this was valuable information, some suggesting this was evidence of the inapplicability of the model, and others arguing that this supported the use of the EPA Default Model in risk assessment and applying different risk management strategies in these areas. Comments were received suggesting that it was inappropriate, according to EPA guidance, to evaluate short-term exposures using the IEUBK and that, if employed, longer averaging times should be used. Reviewers from EPA's Technical Review Workgroup for lead (TRW) disagreed and, conversely, suggested shorter averaging periods for these exposures.

9a General Response regarding the Applicability of the IEUBK "Box" and EPA Default Models: *The IEUBK model is a series of mathematical equations that simulates the behavior of lead taken into the body. The model has an intake component that estimates how much of the lead is taken into the body from five main routes of exposure. Those exposure routes include lead from the diet, drinking water, soil and dust, air and other incidental ingestion sources, such as paint or consumer items. The uptake portion of the model then estimates how much of the intake lead is absorbed in the body, and the bio-kinetic portion distributes that absorbed lead among body tissues and excretes the remainder. The model provides predictions of mean blood lead levels for 0-7 year-old children in one year age increments. The mean blood lead estimate can be interpreted as the most likely response expected for the typical child exposed to those particular environmental conditions. In a follow-up step, probabilistic methods are used to estimate the distribution of blood lead levels for a population exposed to those conditions. In comparison to risk assessment methodologies used for other contaminants, such as that accomplished for several metals in Section 5 of the HHRA, the IEUBK is neither simplistic nor generic. The model allows for input of site-specific environmental data, exposure factors and route specific absorption rates; integrates the effects of lead deriving from different routes; and relates the biological response directly to toxicity criteria on an age-specific basis. This procedure is considerably more complex than that applied in non-carcinogenic risk assessment, and results in more precise and less uncertain estimates of effect, than is typically obtained. As a result, lower margins of safety are employed in sub-chronic lead risk assessment than in the methods used for other metals.*

The IEUBK has been extensively reviewed by the EPA, including reviews by the Science Advisory Board (SAB), and subsequent guidance reflecting these reviews was issued approving the IEUBK for sub-chronic risk assessment for lead in children. These guidance documents are provided in Appendix O. None of the other bio-kinetic simulation models suggested by reviewers have been similarly reviewed, nor has any guidance been issued regarding use of these alternate *techniques. EPA guidance does recognize site-specific empirical modeling of blood lead levels and dose-response as a useful tool to supplement IEUBK analysis. That analysis was accomplished in the HHRA and is discussed in General Response to Comments # 3 and 4. EPA guidance also recognizes that site-specific parameters can be input to the IEUBK model, provided those parameters are representative of site conditions. Four applications of the IEUBK were presented in the HHRA, to provide reviewers and risk managers with alternative analysis for consideration in developing risk management strategies. Those applications included both the community and batch mode versions of the model using nationally representative assumptions for soil and dust ingestion rates and absorption factors in the EPA Default Model application. Similar applications of the site-specific Box Model developed at the BHSS were also presented in the HHRA. The Box Model uses site-specific parameters developed at the BHSS.*

The most significant differences in the EPA Default and Box Model is that the Box Model considers that a significant portion of the soil typically ingested by children derives from the local community and neighborhood and assumes that 18% of the lead in soil and dust is absorbed. The EPA Default Model assumes that all soil derives from the home yard and that 30% of the soil/dust derived lead is absorbed. With respect to pathways, the parameters in the Box Model were derived from structural equation analysis conducted on more than a decade of data collected at the BHSS. The inclusion of soil sources from outside the home yard is frequently applied in IEUBK analysis, if there is reason to believe that children access these soils. In the BHSS, both structural equations and general linear multiple regression analysis indicate that community and neighborhood soils are significantly related to blood lead levels. Pathways analysis indicates that about 40% of soil and dust exposure derives from house dust, with 30% coming from the home/immediate neighborhood and 30% from the greater community. Follow-up investigations of children with high blood lead levels indicate that neighborhood and community soils are important sources in children's exposure profiles.

Several reviewers question whether these same pathways are applicable to the Basin. Site-specific quantitative regression analysis relating blood lead and soil and dust lead levels indicate similar levels of significance and coefficient, or slope, values for the Basin and BHSS populations. These analyses, found in Section 6.4, suggest that the same pathways are involved in both areas at similar magnitudes. Additional discussions are included in General Response # 3a-d, 4a, 7a-b, and 8a. There do seem to be differences between the upper and Lower Basin with respect to this question. The primary sources, communities, demographics and socio-economic factors suspected to influence lead exposures in the Box have more in common with the upper Basin than in the Lower Basin. Most of the children in the upper Basin live in communities of similar size, history, housing characteristics and infrastructure to that of the BHSS area. Mineral industry activities were common throughout the history of the BHSS and the upper Basin influencing both the sources present and the character and economies of the local communities. Relatively high levels of community and residential soil and household dust lead are noted for the upper Basin.

The Lower Basin is more rural in character than the BHSS and upper Basin, with homes being located in the countryside or small unincorporated villages with limited infrastructure. Residential soil and dust lead concentrations are low for homes outside the Coeur d'Alene River floodplain. Residents of the Lower Basin have been more dependent on agriculture, and natural resource industries other than mining. The age of housing, income and poverty indices noted for Shoshone County and the upper Basin are not so evident in the Lower Basin and Kootenai County. Follow-up evaluations of children with high blood lead levels indicate potentially high exposures related to residential soils and dust in upper Basin communities, as opposed to extended recreational activities in the Lower Basin. Both of these observations are consistent with plausible interpretations of the results of IEUBK model assessments. Residential soil and dust exposures largely explain excess lead absorption in the upper Basin in a manner similar to that observed in the BHSS. High blood lead levels in the Lower Basin are explained by incremental recreational activities.

9b General Response regarding Bioavailability Estimates used in the IEUBK Model:
Reviewers have also questioned the appropriateness of applying the 18% bioavailability factor from the Box Model to the Basin. The dose/response relationship between blood lead and soil and dust exposures at the BHSS has long been noted to be reduced from that inherent in the default assumptions of the IEUBK model. In previous analysis, for practical purposes, the reduced effect has been attributed to lowered bioavailability of the soils and dust. The 18% absorption factor also results from analysis of the last twelve years of paired blood lead and environmental exposure data from the BHSS. The value was derived by estimating absorbed lead levels, or uptake, from observed blood lead levels using bio-kinetic factors common to the IEUBK Model. Bioavailability was determined empirically by relating uptake to estimated intake rates calculated by multiplying soil and dust lead concentrations by ingestion rates, also consistent with the IEUBK model. This method has the effect of attributing the reduced dose/response to lowered bioavailability. It is also possible, however, that children in the BHSS may exhibit lower ingestion rates than those assumed in the IEUBK model. There is reason to believe that ingestion rates may be depressed due to the ongoing long-term intervention and education programs that have sought to reduce lead intake through behavioral modification. If that were the case, then bioavailability would be greater than 18%. Similarly, the practice of using a 175 micron sieve for soils and dusts could potentially increase soil and lead concentrations above that expected from 250 micron sieve recommended for input to the IEUBK. This also would result in higher bioavailabilty being calculated for the BHSS. As a result, for the BHSS the 18% figure for bioavailability should be regarded as a minimum. The actual value could be higher if ingestion rates are less than the default assumptions. It is less likely that the effective bioavailability is lower than the 18% estimate.

A similarly reduced dose/response relationship is noted between observed blood lead levels and measured soil and dust lead concentration in the Basin. Some reviewers have suggested that Basin-wide ingestion rates may also be suppressed due to the same intervention and education efforts being extended to the Basin and the general knowledge of lead-related hazards in the area. The 175 micron sieve is also used to prepare soil and dust samples in the Basin. Both of *these factors would suggest that bioavailability may be higher than 18% in the Basin as well. However, there are other plausible arguments for lower bioavailability in the Basin than the BHSS. Soil and dust contamination in the BHSS was influenced by pyro-metallurgically processed ores from the smelter complex. These ores were released to the environment in predominantly lead oxide forms, whereas, the majority of ores released from mining and milling operations were released as lead sulfides. Generally, lead sulfide species are less soluble and less bioavailable than lead oxides.*

However, there are also reasons to suspect that mill and mine tailings releases have undergone secondary mineralization in the environment and are no longer sulfide minerals. Milling practices conducted through most of the twentieth century did not effectively capture oxidized lead in the concentrating process. As a result, oxidized forms of lead in the original ores, present in near surface ore bodies, were preferentially discharged. The soil and dust particles that children access are generally small, in the <150 micron range, and more available for ingestion because of frequent hand-to-mouth activity. That is, smaller particles adhere to hands and are ingested orally. These small particles have been in the environment for several decades, many being discharged a century ago. There has been mechanical abrasion and much reworking of tailings due to human and stream activities. This decreases particle size and increases surface area to volume ratios providing increased exposure to air and more reaction sites for oxidation to occur. During this time, those tailings that reach children, i.e., the smallest particles at the ground surface, have been exposed to the atmosphere and aerobic hydrologic conditions. As a result, the particles or the surface fraction have become oxidized and are more bioavailable to children. Electron microscope images of lead particles in this size range often show oxidized surface inclusions that can be dissolved even on chemical species that are otherwise relatively unsoluble. As time goes on, these particles will only become more oxidized and more bioavailable unless confined to anaerobic conditions. As a result of all these factors, it is unlikely that the particles ingested by children are purely a sulfide form and are less likely to be in the future. This conclusion is not inconsistent with the results of the swine studies conducted in Region VIII of the EPA. Several tailings and sulfide ore wastes were found to be bioavailable. The overall results of those investigations suggest that average bioavailability of all wastes and soils tested reflects the 30% bioavailability default advocated by EPA. The 18% used in Idaho is actually on the low side of bioavailability observed across the range of potential sources. These studies are summarized in Appendix O.

9c General Response regarding the GSD used in the IEUBK Model: *Comments were also received regarding the appropriateness of the geometric standard deviation (GSD) employed in predicting the distribution of blood lead estimates relative to the mean predicted by the IEUBK model. The HHRA used the default GSD value of 1.6 recommended by current EPA guidance. That GSD is applied to the mean blood lead estimate determined by the IEUBK and reflects the variation in outcome blood lead levels for the exposed population. The result, if applied to a population, can be presented and interpreted as the percent of children expected to exceed critical toxicity or blood lead levels. If applied to a particular exposure situation, the result can be presented and interpreted as the probability that an individual would exceed that criteria. In* *the community mode IEUBK application, the GSD is applied to a mean blood lead estimate resultant from, among other factors, the mean community-wide soil and dust lead concentrations. The GSD that is applied should reflect both the inherent individual variation in response and the variation in exposure. In the batch mode application, mean blood lead estimates and probabilities are determined for each individual situation and the results are aggregated to estimate a community mean and percent to exceed criteria for the community. In this case, the overall GSD for the community is calculated from the aggregate risk, and represents both the inherent individual and exposure-related variation. In the batch mode, the mean blood lead level and probability to exceed toxicity criteria can also be determined and applied to the individual situation. For the individual situation, the GSD reflects only the inherent variation in response among individuals. The default GSD recommended by the EPA is representative of a number of investigations with varying degrees of exposure variation inherent in results. Applying the typical GSD value of 1.6 to individual situations could overestimate the probability of exceedance for the individual. Risk managers may want to consider the application of the 1.6 GSD in the batch mode application as an additional margin of safety when considering the probability of an individual exceeding toxicity criteria. This consideration would not apply to the community-wide estimates of the percent of the population to exceed these criteria.*

9d General Response regarding Observed and Predicted Blood Lead levels from the IEUBK Model: *Several comments were received regarding the ability of the IEUBK to predict observed blood lead levels. Several comparisons of predicted and observed blood lead levels were included in the HHRA. Many comments were received regarding the representativeness of the observed blood lead data set. This issue was discussed in detail in Sections 7.4 and 8.11 of the HHRA and additional discussion is included in General Response to Comments # 2. There are several considerations with regard to what are the appropriate comparisons between the model projections and observed blood lead levels. One comment was received suggesting that observed and predicted blood lead levels are totally unrelated data sets and any comparison is improper. This conclusion is incorrect. The relationship between blood lead levels and environmental exposures is examined throughout the HHRA by a variety of methods. In regression analysis, such as the site specific quantitative models discussed in General Response to Comment # 4, it is common practice to compare dependent blood lead levels predicted from independent exposure variables to observed concentrations. In IEUBK analysis, the same independent exposure variables are input to a mechanistic model and outcome blood lead levels are predicted. It is also common to compare these predictions to observed blood lead levels. In both cases, the blood lead and environmental levels are related. Both the dependent and independent variables come from the same home and community and the purpose of the analysis is to investigate and quantify any relationship between the variables. The regression analysis discussed above shows a relatively strong relationship, that is consistent with plausible environmental and biological processes, and is similar to the findings of investigations at other sites including the BHSS. As a result, it is appropriate to compare predicted and observed blood lead levels in both empirical and mechanistic procedures.*

However, it is important to note that the IEUBK model predicts the mean, or most likely response, to the exposures represented in the model input. The model also provides the probability that higher or lower blood lead levels may be observed. As a result in comparing individual blood lead levels to IEUBK projections, the distribution of probable results must be considered. An individual observed blood lead may reasonably fall within the overall distribution of probable blood lead levels. For example, for a mean blood lead prediction of 5 μg/dl with a GSD of 1.6, approximately 68% of children so exposed would be expected to have a blood lead level between (5/1.6=)3.1 μg/dl and (5x1.6=)8.0 μg/dl, and 95% of children would have levels between (5/1.6/1.6=)2.0 μg/dl and (5x1.6x1.6=)12.8 μg/dl. In comparing observed and predicted levels from the IEUBK, it is necessary to compare the mean projection and distribution of responses. These comparisons are made in Section 6.7 of the HHRA. Examination of these results show that the observed mean blood lead levels in the upper Basin are best described by the Box Model and in the Lower Basin by the EPA Default Model. Similarly, the percent to exceed 10 μg/dl is best described by the batch mode of the same IEUBK models. Finally, it is important to note that neither the Box Model or the EPA Default model were calibrated or otherwise adjusted in response to, or to reflect, Basin blood lead levels. The site-specific or default parameters used in these models were developed from either analysis of data from the BHSS or national observations, respectively. One disadvantage of this methodology is that the number of observations that can be directly compared is limited to the number of communities examined, or for the Basin, eight comparisons.

The record for the BHSS is large with 5 communities being observed for 13 years. Appendix Q to the HHRA summarizes the results of applying the Box and Default models to the BHSS and figures are included showing predicted and observed mean blood lead levels for the entire period. These figures, the supporting discussions and analysis in Appendix Q suggest that the Box Model has effectively predicted blood lead levels in the BHSS for more than a decade. The EPA Default model has been nearly as effective a predictor in recent years, but tended to over-predict in earlier years.

Determining which model performs most effectively for the Basin depends on several of the issues discussed in the HHRA, reviewers comments and response to those comments. The Box Model effectively predicts both mean blood lead levels and percent of children to exceed 10 μg/dl in the upper Basin, in a manner consistent with its performance in the Box over the last decade. Risk managers could consider the Box Model appropriate to characterize risk in the Basin provided that similar pathways and dose-response relationships are involved and that the blood and environmental lead levels evaluated in the model are representative of the Basin population. There are questions as to whether the observed blood lead levels are representative of the overall Basin population. Regression analysis relating blood lead and environmental lead levels suggest similar pathways, with somewhat lower slope values for soil and dust concentrations in the Basin. There are many similarities among the BHSS and upper Basin communities from size, socio-economic, history, industry, economy, size, infrastructure, and demographic perspectives. There are reasons to suspect that a somewhat lower dose/response *rate with soils could be associated with mine-related to smelter-related sources of lead in the community.*

10 Comments Related to Interpretation and Discussion of Applicable Rules, Regulations and Guidance: Several comments were received regarding interpretation and discussion of EPA and other federal guidance in the HHRA. Some comments indicated that the HHRA provides inappropriate risk management discussions and that those presentations bias the document toward particular risk management decisions. Some comments suggest that the HHRA is pre-disposed toward soil cleanup and ignores intervention-directed risk management strategies. The same comments also indicated that multiple-safety factors incorporated into the analysis and federal guidance requirements result in pre-determined cleanup levels beyond the level of diminishing returns. Other comments indicate that the HHRA is biased toward use of the Box Model in eventual cleanup decisions, and as a result, is not protective. These reviewers believe federal guidance requires the use of the EPA Default Model and that there is insufficient site-specific data to justify other models or risk management methods. These reviewers suggest that EPA guidance requires primary (i.e., preventative) risk management responses and that intervention activities are secondary measures non-compliant with guidance. Several comments referred to the EPA's guidance regarding protection of individual children versus percentages of the general population and there were differing views of the appropriateness and interpretation of Public Health Service and federal Centers for Disease Control (CDC) guidance on these matters. Some reviewers felt the HHRA was over-protective, while others felt too many children were left at risk under these interpretations. Comments were also received regarding inconsistencies in federal lead exposure and risk assessment/risk management requirements. These reviewers point out that federal OSHA standards require maintenance of adult occupationally exposed female blood lead levels less than 30 μg/dl as protective of the fetus, as opposed to the Public Health Service and EPA's adoption of the 10 μg/dl criteria. Comments also pointed out that federal Housing and Urban Development (HUD) guidance advises soil cleanup levels as high as 5000 mg/kg lead in contrast the EPA Default Model, de facto, 400 mg/kg level. Other comments pointed out that Tribal risk assessment policies that are more stringent than EPA guidelines have been ignored in the HHRA. Comments were also received regarding the appropriateness of lead toxicity discussions in both the HHRA and EPA guidance. Some reviewers felt the document failed to differentiate among potential adverse effects with respect to different levels of exposure. These reviewers objected to terminology used with respect to "lead poisoning" and "rates of toxicity" in the population and believed that all potential effects should be discussed in relation to the blood lead levels observed in the Basin. These reviewers also indicated that the discussions do not reflect the likelihood and severity of effects consistent with Basin blood lead levels, and as a result overstate the risk of adverse effects. Conversely, other reviewers believe that the risk and severity of effects associated with lead are understated because the chronic effects of lead poisoning are not considered additive to other contaminant risks in non-carcinogenic assessments under current EPA policy.

10a General Response regarding Risk Assessment versus Risk Management Issues: *Numerous comments addressed eventual risk management issues associated with the HHRA. The purpose* *and objectives of the HHRA are to assess the potential risk of adverse human effects associated with contaminated environmental media in the Coeur d'Alene Basin. Risk assessment identifies those contaminants, media, pathways, sources of contamination, routes of exposure, and potential for human intake that could pose unreasonable risk. The risk assessment process does not determine cleanup strategies or criteria for contaminated media. In situations similar to the Basin, however, public health authorities have found excess absorption to be occurring and preventative actions are in place. Risk management activities are already underway in the form of a lead health intervention program being locally implemented and focused remedial actions being conducted under emergency authority. The adjacent Bunker Hill Superfund Site (BHSS) has been implementing a variety of cleanup actions and risk reduction measures for more than a decade, many of which were the genesis of Basin-related activities. As a result, the HHRA does, to the extent possible, consider and review the information obtained, the relationships observed and lessons learned in the numerous efforts to eliminate lead poisoning among the children of the Silver Valley over the last three decades. Actual measurements of blood lead data paired with environmental exposures from a substantial portion of the population were used to identify site-specific factors that influence absorption in the Basin. Quantitative regression analysis was accomplished to identify site-specific relationships among blood and environmental lead levels. The follow-up records of dozens of children with high blood lead levels were gathered. Clues to both environmental sources and factors that influence the potential for excess absorption were identified and discussed. Finally, a site-specific bio-kinetic model that has accurately predicted blood lead levels and responses to remedial activities at the BHSS was utilized and the results contrasted with conventional risk assessment techniques.*

These efforts have resulted in a lengthy, complex and comprehensive HHRA. This information has been presented, analyzed, evaluated, and discussed in Sections 1 through 6. Section 6 also provides discussions and analysis of the various factors and relationships that help to define the potential blood lead absorption problems in the Basin for the consideration of risk managers. Both qualitative and empirical relationships are derived and presented. This analysis was developed at the request of State of Idaho health authorities to aid in developing a comprehensive risk management strategy for the Basin. Section 7 discusses the uncertainties associated with the entire HHRA. In whole, the HHRA provides risk managers, the public, reviewers and other interested parties with information to independently evaluate developing effective risk management strategies. Determinations regarding particular elements of the eventual strategies and compliance with applicable State, federal or Tribal ARARs is a determination that is addressed in the Feasibility Study (FS), risk management process, and Proposed Plan for the site.

10b General Response regarding Compliance with the NCP and Risk Assessment Guidance and Policy: *With respect to guidance specific to the risk assessment process, the methods employed are compliant with applicable EPA guidance and the National Contingency Plan. EPA guidance on conducting risk assessments specific to human health hazards associated with lead were included in Appendix O in the HHRA and as Appendix D to the December 2000, Human Health Alternatives Technical Memorandum. EPA risk assessment guidance includes the 1994*

OSWER Directive #9355.4-12 Revised Interim Soil Lead Guidance for CERCLA Sites and RCRA Corrective Action Facilities and the subsequent 1998 OSWER Directive #9200.4-27P Clarification to the 1994 Revised Interim Soil Lead Guidance for CERCLA Sites and RCRA Corrective Action Facilities. These directives recommend the IEUBK Model as a primary tool for lead risk assessment, describe the objective of limiting individual risks of having a blood lead level of 10 μg/dl or greater to no more than a 5% probability and focusing action preventing exposure rather than intervention after an exposure has occurred. Additionally, these directives clarify shared objectives and distinctions in the CERCLA, RCRA, and TSCA approaches to lead risk assessment and remedial response. A common objective is prevention of exposure to lead, based on use of the IEUBK model to predict risks from environmental sampling data, rather than relying on elevated blood lead levels as a guide to response actions. Specific considerations of the use of observed blood lead information in concert with modeling results are discussed in detail.

Excerpted from OSWER Directive #9355.4-12

> *In all three of these programs (CERCLA, RCRA, and TSCA Section 403), the Agency's approach is to consider soil lead in the context of other lead sources that may be present and contribute to the total risk. For example, TSCA Section 403 specifically requires the hazards posed by lead-based paint and lead contaminated interior dust, as well as lead-contaminated soil. Likewise, the OSWER Soil Directive includes evaluation of other lead sources as part of site assessment / investigation procedures. In addition, the primary focus of the three programs is primary prevention — the prevention of future exposures from the source(s) being remediated.*

Excerpted from OSWER Directive #9200.4-27P

> *At lead contaminated residential sites, OSWER seeks assurance that the health of the most susceptible population (children and women of child bearing age) is protected and promotes a program that proactively assesses and addresses risk. OSWER believes that predictive tools should be used to evaluate the risk of lead exposure, and that cleanup actions should be designed to address both current and potential future risk.*
>
> *While health studies, surveys and monitoring can be valuable in identifying current exposures and promoting improved public health, these are not definitive tools in evaluating potential risk from exposure to environmental contaminants. In the case of lead exposure, blood lead monitoring programs can be of critical importance in identifying individuals experiencing potential negative health outcomes and directing education and intervention resources to address those risks. However, CERCLA 12(b) requires EPA to select cleanup approaches that are protective of human health and the environment and that utilize permanent solutions to the maximum extent practicable. To comply with the requirements set forth in CERCLA 12(b), OSWER will generally require selection of cleanup programs that are proactive in mitigating risk and that do not simply*

rely on biological monitoring programs to determine if an exposure has already occurred.

To meet these objectives, OSWER will seek actions that limit exposure to soil lead levels that a typical child or group of similarly exposed children would have an estimated risk of no more than 5% of exceeding 10 µg/dl blood lead level. If lead is predicted to pose a risk to the susceptible population, OSWER recommends that actions be taken to significantly minimize or eliminate this exposure to lead.

Prevention of lead exposure is critical because adverse health effects resulting from lead exposures to young children persist into adulthood.

10c General Response regarding Applicable or Relevant and Appropriate Requirements (ARARs): *Comments were received referring to HUD soil cleanup guidelines indicating that HUD and EPA guidance exists for soil lead action levels from 400-5000 mg/kg, that this guidance allows methods other than soil abatement as a remedy, and that EPA sanctioned biological monitoring and reactive intervention strategies in lieu of soil remediation at the Leadville site in Colorado. Presumably, these comments are in reference to activities in regulatory programs other than Superfund and how these regulations are applied in CERCLA (Comprehensive Environmental Response Compensation and Liability Act), RCRA (Resource Conservation and Recovery Act), and TSCA (Toxic Substances Control Act). With respect to the soil action criteria, consideration of interim Title IV º403 of TSCA is described in various EPA-OSWER directives. These regulations are not considered to be ARARs by the EPA. TSCA º403 guidance should be evaluated separately from the OSWER program guidance as the former mainly addresses concurrent soil abatement associated with lead paint removal programs in largely urban areas. Three EPA OSWER directives address consideration of this guidance in CERCLA and RCRA actions: (1) #9355.4-12, EPA/540/F-94/043, August 1994; (2) #9200.4-27, EPA/540/F-98/030, August 27, 1998; (3) # 9200.4-29, EPA 540-F-98-061, December 1, 1998. These documents are included in Appendix O to the HHRA. The 12/1/98 guidance discusses soil clean-up levels addressed in Title IV TSCA º403 and both CERCLA and RCRA sites:*

[par. 1 of Directive] "...questions have been raised about the relationship between the proposed TSCA º403 rule [proposed June 3, 1998] and the Office of Solid Waste and Emergency Responses' Interim Soil Lead Guidance for CERCLA Sites and RCRA Corrective Facilities (OSWER Directive #9200.4-27P, August 27, 1998)." [p. 2, par. 1 of Directive] "EPA has proposed a 2,000 ppm hazard standard for lead in soil at which children's exposures will be associated with a greater certainty of harm...The hazard standard was intended as a "worst first" level that will aid in setting priorities to address the greatest risks promptly. The proposed º403 regulations and the accompanying guidance are to be used by Federal, State, and Tribal lead paint programs, as well as by the industry performing inspections and risk assessments."

[p. 2, par. 3, "OSWER's Soil Lead Directive"] "The OSWER soil lead directive that

provides guidance for the cleanup of lead-contaminated sites under the CERCLA and RCRA laws is unaffected by this proposal. CERCLA and RCRA soil lead clean-ups should follow the approach in the 1998 directive...The TSCA º403 proposed 2,000 ppm hazard level should not be treated as an Applicable or Relevant and Appropriate Requirement (ARAR), "to be considered" or TBC or media cleanup standard (MCS). As recognized in the TSCA º403 rule, lead contamination at levels below 2,000 ppm may pose a serious health risk based upon a site-specific evaluation and may warrant timely response actions. Thus, the 2,000 ppm proposed standard under TSCA º403 should not be used to modify approaches to addressing Brownfields, RCRA sites, National Priority List (NPL) sites, Federal CERCLA removal actions, and CERCLA non-NPL facilities."

[p. 3, 1st full par.] "In the absence of site-specific information, EPA believes that levels above 400 ppm may pose a health risk to children through elevated blood lead levels. The 400 ppm screening level identified in the OSWER soil lead guidance is consistent with the "level of concern" identified in the preamble to the proposed TSCA º403 rule."

With regard to cleanup levels established at the Leadville site, the remedial action is an actively monitored pilot program that is specifically intended to set no precedent nor serve as an example for response actions at other sites. The record of Decision (ROD) for the site specifically states that "... Because this decision will result in hazardous substances remaining on-site, above health based levels, five-year reviews of this response action will be required." The Leadville cleanup is experimental and the efficacy of this ROD will be evaluated as a pilot project at prescribed interval by a group of outside reviewers.

Some comments pointed to an apparent discrepancy in federal blood lead standards for reproductive aged females between EPA public health policy of 10 μg/dl and the Occupational Health and Safety Administration (OSHA) worker protection 30 μg/dl requirement. OSHA standards are not considered ARARS by the EPA. There are two principal reasons for the treatment of OSHA standards as non-ARARs in the NCP. First, Congress appears to have intended that certain OSHA workplace standards apply directly to all CERCLA response actions. Second, EPA believes that OSHA is more properly viewed as an employee protection law rather than an "environmental" law, and thus the process in CERCLA section 121(d) for the attainment or waiver of ARARs would not apply to OSHA standards (55 FR 8679).

Moreover, OSHA does also state that "the blood lead levels (BLL) of workers (both male and female workers) who intend to have children should be maintained below 30 μg/dl to minimize adverse reproductive health effects to the parents and to the developing fetus." However OSHA then goes on to say that, "There is a wide variability of individual response to lead, thus it is difficult to say that a particular BLL in a given person will cause a particular effect. BLL measurements show the amount of lead circulating in your blood stream, but do not give any information about the amount of lead stored in your various tissues. BLL measurements merely show current absorption of lead, not the effect that lead is having on your body or the effects that past lead exposure may have already caused." [57 FR 26627, May 4, 1993, as amended at 58 FR 34218, June 24, 1993]

The 10 μg/dl value is a default value used in the Adult Blood Lead Model recommended by the Technical Review Workgroup for Lead (TRW). The basis for using 10 μg/dl is that fetuses and neonates are a highly sensitive population with respect to the adverse effects of lead on development, and 10 μg/dl is considered to be a blood lead level of concern from the standpoint of protecting the health of sensitive populations, such as the developing child (U.S. EPA, 1986, 1990; NRC, 1993). The basis for selecting the value of 10 μg/dl is based upon a combination of reviews by the Environmental Protection Agency, the Agency for Toxic Substances and Disease Registry, and the Centers for Disease Control. [see proposed rulemaking for 403 for details]

The purpose of the adult blood lead model is to predict PRGs (preliminary remediation goals) and not govern blood lead levels monitored in the workplace. The value of 10 μg/dl used in the model is based on the need to protect the health of children, and is therefore, used as a risk-based value in the model. Also, OSHA does not have a direct conflict with EPA's practice of its adult model for setting PRGs.

Pertinent memoranda are cited and/or included in the Appendices to the document.

10d General Response regarding Data Quality Objectives Guidance: *Three EPA guidance documents on data sampling and analysis were not cited in the HHRA and comments questioned whether appropriate guidance had been followed. The three documents cited were: 1993, Data Quality Objectives (DQO) Process guidance; 1998, Data Quality Assessment (DQA) guidance; and 1992, Data Usability in Risk Assessment. All three guidance documents were followed and are discussed in varying degrees in the individual FSPAs and the RI/FS. The following is a brief summary of how these guidance documents were applied to the Baseline HHRA.*

A. The purpose of the 1994, Guidance for the Data Quality Objectives Process is to provide general guidance to organizations on developing data quality criteria and performance specifications for decision making. The DQO process is a strategic planning approach that provides a systematic procedure for defining the criteria that a data collection design should satisfy, including when, where, and how many samples to collect and the tolerable level of decision errors for the study. The seven step DQO process was considered and documented in the Draft Technical Work Plan (URS Greiner and CH2M HILL 1998), and considered further and documented in varying degrees in the individual FSPAs developed from 1997 through 2000. Each FSPA and USGS task was developed to address specific data gaps identified after reviewing available historical data and results of previous sampling and analysis efforts. The purpose of each data collection effort was to investigate areas potentially impacted by mining related activities. Due to the large geographic extent of the study area, it was not possible to fully characterize all areas. As all data gaps were not addressed, subsequent studies of specific areas identified for remedial actions may be needed to support remedial design efforts.

B. The DQA Process is a comparison of the implemented sampling approach and the resulting analytical data against the sampling and data quality requirements specified by the DQOs.

Results of the DQA are used to determine whether data are of adequate quality and quantity to support the decision-making process. The data quality assessment performed for this study includes evaluation of the quality of the analytical data generated for each of the field sampling efforts and evaluation of the adequacy of the data set in meeting the intended data uses. To provide a high level of quality for the analytical data collected during this study, samples were submitted to commercial laboratories or to EPA for analysis using the EPAs contract laboratory program (CLP) methods or the EPA SW-846 methods. High quality is maintained in these programs through the use of on-site audits, performance evaluation samples, quarterly performance reports, fraud detection mechanisms, performance based scheduling and continuous inspection of laboratory data. Additionally, all analytical data were validated according to EPA data validation guidance (EPA 1994). Following validation, the data set was further reviewed for proper application of data qualifiers. Data identified during validation as being unacceptable for project uses were not carried forward in the assessment.

The sampling plans were designed to provide data to be used in determining if areas are impacted and to support risk assessment activities. Because all surveys have an associated measurement error and risk assessment requires a high degree of certainty, field sampling and analysis plans are designed with a known confidence level (95 or 99 percent) for the majority of common use area sampling. The majority of residential soil concentration data, however, was developed from pre-existing surveys and volunteer results from individual requests to be evaluated for emergency removal programs. These surveys did not have pre-specified confidence levels. The methodology employed was developed to support the 1996 IDHW/ATSDR exposure study conducted in the Basin. This methodology mirrored the sampling procedures used at the BHSS for the last two decades. These methods were developed in compliance with DQO and DQA requirements and have been extensively reviewed. Utilizing these data and the associated site-specific blood lead observations obtained through IDHW/ATSDR/PHD health response programs was a fundamental precept to conducting the risk assessment in parallel with the RI/FS. Comparisons of the results of the sampling methodologies combined to develop the data base supporting site-specific analysis is presented in Appendix N. Uncertainties associated with using the information generated in the earlier Basin investigations and combining data from different sampling efforts is discussed in Section 7 of the document.

Specifying confidence levels in advance of sampling is important when defining sites where it is difficult to determine if an area has been impacted by contamination (average concentration close to screening values). Where historical information clearly indicates areas are contaminated (average concentration much greater than screening value), specifying confidence intervals prior to sampling is not necessary because the probability of falsely characterizing the area are low. Residential soil lead levels in the Basin have been shown to be impacted and exhibit substantially higher lead concentrations than communities with similar demographic and socio-economic conditions. High blood lead levels among children has been documented and health response activities have been undertaken with respect to soil exposures. Subsequent sampling events have confirmed the initial assumption.

C. The 1992, Final Guidance for Data Usability in Risk Assessment provides practical guidance on how to obtain an appropriate level of quality of all environmental analytical data required for Superfund human health risk assessments. This guidance complements and builds upon other Agency guidance documents such as the 1989, Risk Assessment Guidance for Superfund (RAGS) and the DQO guidance mentioned above. The four data application questions requiring an answer for risk assessment from the 1992 guidance are as follows:

1. What contamination is present, and at what levels? - The extent of contamination in the Basin is addressed in Section 2 of the HHRA which describes sample collection methods, data analysis procedures (metals), and notes where samples were collected specifically for human health needs versus other uses. The vast majority of the data used in the HHRA was collected based on human health considerations and fulfills the requirements of risk assessment guidance described in RAGS and in the 1992 document. For the relatively small amount of data used that was not collected for HHRA use (sediment and surface water data in the South Fork, Canyon Creek, and Nine Mile Creek), the uncertainties associated with these data are discussed in both Section 2 and in Section 7 of the report. Other than the data noted above and the special case of waste piles, all samples were collected using a randomized or systematic sample design appropriate for risk assessment evaluations.

2. Are site concentrations different from background? -- Section 2 presents background concentrations for applicable media (except groundwater) and selected COPCs based on concentrations exceeding background levels and health levels.

3. Are all exposure pathways identified and examined? -- Exposure pathways were discussed and conceptual site models by human health geographic areas were presented in Section 3.

4. Are all exposure areas fully characterized? - Human health exposure areas were discussed in Section 3. However, they were not explicitly defined in many cases due to the large and complex area of the Basin. Additional data may be required to support remedial design and remedial action activities on a site-by-site basis for individual sub-areas of the Basin.

11 Comments related to the Adult Exposures to Lead in Soil Model: Several comments were received pertaining to uncertainty associated with using default values in the model. Other comments regarding the Adult Lead Methodology (ALM) suggested that data supporting the GSD for adults is limited and will result in overestimating risk. Comments also indicated that the 12% absorption default value used in the model should be lowered. A few comments also questioned the blood lead value of 10 μg/dl used in the model when OSHA monitors for blood leads of 30 μg/dl in pregnant woman working in lead contaminated areas. The TRW review also provided comments regarding the uncertainty associated using the ALM for infrequent exposure periods, the averaging time used, the soil weighting factor, and explorations into the use of site-specific blood lead levels.

11a General Response Regarding Adult Exposures to Lead in Soil Model: *The TRW recommends that the ALM not be used for exposure frequencies less than 3 months. The CT occupational exposure scenario assumes a two month construction period where the EF is 8.7 weeks per year for 5 days a week. This EF is the only scenario not meeting ALM criteria and will result in greater uncertainty, possibly overestimating risk. However, the averaging time* *used in the ALM was for exposure over a 365-day period instead of over the exposure duration, which would result in higher PRGs, or underestimating risk. The averaging time of a 365-day period was used for all (i.e., both occupational and the 4 recreational) scenarios. As a result, for the recreational and RME occupational scenarios, risk may be underestimated. The TRW also suggested to explore alternative assumptions for baseline blood lead input to the model, given the blood lead data collected at the site. The guidance to the ALM states, "Ideally, the value(s) for PbB(adult, 0) used in the methodology should be estimated in the population of concern at the site. This requires data on blood lead concentrations in a representative sample of the adult women who are not exposed to nonresidential soil or soil-derived dust at the site...The sample must be of sufficient size to yield statistically meaningful estimates of PbB(adult, 0)" (TRW 1996). The geometric mean female adult blood lead level was 2.0 μg/dl and ranged in the 8 geographic areas from 1.6-2.6 μg/dl. If the scenarios were applied to each geographic area as was done for children in the IEUBK, the total number of samples from each area was not of sufficient size (n=12-41, see Table 6-8b) to yield statistically meaningful estimates able to change the default value. A national value of 1.7 μg/dl was used in the risk estimates. If the Basin-wide geometric mean of 2.0 μg/dl were applied, higher blood lead levels and lower PRGs would be estimated. As a result, risk managers may consider risk somewhat underestimated for all but the short-term construction scenario. The TRW also pointed out that a soil weighting factor of 1 was used in equation 2 of the ALM (Tables 6-57 through 6-60b) and the HHRA agrees that the two approaches do not differ. These columns in Tables 6-57 through 6-60b will be deleted in the final document.*

11b General Response Regarding Default Values: *One comment stated that the model uses all default values, resulting in high uncertainty. The HHRA actually uses site-specific exposure frequencies and soil ingestion rates for consistency with the non-lead portion of the document. Blood lead values (as described in 11a) were not changed because site-specific values were not significantly different. The uncertainty associated with the model is discussed in Section 7.4 of the HHRA. One comment suggested that the default GSD value is estimated from limited adult data and will overestimate risk. The default GSD values used in the ALM are 1.8-2.1. Site-specific GSD values range from 1.6-2.2 in the geographic areas, and are not dissimilar to the default values. One commenter suggested that the infrequent exposure periods would increase uncertainty and overestimate risk. As discussed in 11a, the HHRA agrees that uncertainty may be increased, but there are other factors used in the model that tend to underestimate risk.*

Finally, there were a few comments regarding the use of the default value of 10 μg/dl in the model versus the OSHA standard of 30 μg/dl. The OSHA standard reads as follows:

> *D. "Permissible Exposure": The permissible exposure limit (PEL) set by the standard is 50 micrograms of lead per cubic meter of air (50 μg/m(3)), averaged over an 8-hour workday.*
>
> *E. "Action Level": The interim final standard establishes an action level of 30 micrograms of lead per cubic meter of air (30 μg/m(3)), averaged over an 8-hour workday. The action level triggers several ancillary provisions of the standard such as exposure monitoring, medical surveillance, and training. (3) "Health protection goals of*

the standard". Prevention of adverse health effects for most workers from exposure to lead throughout a working lifetime requires that a worker's blood lead level (BLL, also expressed as PbB) be maintained at or below forty micrograms per deciliter of whole blood (40 μg/dl). The blood lead levels of workers (both male and female workers) who intend to have children should be maintained below 30 μg/dl to minimize adverse reproductive health effects to the parents and to the developing fetus. [57 FR 26627, May 4, 1993, as amended at 58 FR 34218, June 24, 1993]

OSHA states that "the blood lead levels of workers (both male and female workers) who intend to have children should be maintained below 30 μg/dl to minimize adverse reproductive health effects to the parents and to the developing fetus." However OSHA then goes on to say that "There is a wide variability of individual response to lead, thus it is difficult to say that a particular BLL in a given person will cause a particular effect. BLL measurements show the amount of lead circulating in your blood stream, but do not give any information about the amount of lead stored in your various tissues. BLL measurements merely show current absorption of lead, not the effect that lead is having on your body or the effects that past lead exposure may have already caused." [57 FR 26627, May 4, 1993, as amended at 58 FR 34218, June 24, 1993]

The 10 μg/dl value is a default value used in the Adult Blood Lead Model recommended by the Technical Review Workgroup for Lead (TRW). The basis for using 10 μg/dl is that fetuses and neonates are a highly sensitive population with respect to the adverse effects of lead on development, and 10 μg/dl is considered to be a blood lead level of concern from the standpoint of protecting the health of sensitive populations, such as the developing child (U.S. EPA, 1986, 1990; NRC, 1993).

The purpose of the adult blood lead model is to predict PRGs (preliminary remediation goals) and not govern blood lead levels monitored in the workplace. The value of 10 μg/dl used in the model is based on the CDC guidelines to protect the health of children, and is therefore, used as a risk-based value in the model. The purpose of the OSHA blood lead value is to protect workers at Brownfield sites. Also, OSHA does not have a direct conflict with EPA's practice of its adult model for setting PRGs. See also General Response to Comment # 10c.

SECTION 3.0
DR. PAUL MUSHAK'S RESPONSES TO COMMENTS

PB Associates

Memorandum

From: Paul Mushak

To: Sharon Quiring, Sean Sheldrake, Marc Stifelman, Ian von Lindern

Date: 12/15/00

Re: Part 1 Responses: TRW, Dr. Coomes

Part 1: Responses to Public and EPA-TRW Comments on the Draft HHRA

Paul Mushak, Ph.D.

Responses to comments on the draft HHRA are given below and are organized by each commenting group. General responses to the commenter's statements, criticisms and concerns are provided as well as specific responses following the sequence in the comment documents.

I. EPA's TRW for Lead Comments on the Public Draft HHRA

EPA's TRW for Lead review has been extremely helpful and constructive to the purposes and thoroughness of the draft HHRA. The authors should give serious thought to using some of the suggestions. I would, however, like to note the need for elaboration on one matter that the TRW had not adequately dealt with.

The incremental lead intakes portion of the HHRA, to include risk characterizations associated with incremental intakes and Pb-B increases therefrom, appear in TRW, Sec. 2.5. pp. 20-21. The TRW correctly states, 1st full par., p. 21, that the method of incremental risk estimation done in the HHRA underestimates incremental risk because of how the calculations were done. This TRW concern is not only valid but requires further elaboration.

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As the principal co-author of the Introduction and Lead portions of Ch. 7, the uncertainty chapter, I would like to have the following paragraphs added to the addendum of changes in Ch. 7. The best place for addition would be Sec. 7.4.4., p. 7-42, Incremental Blood Levels

"The means by which we first estimate baseline residential scenario blood leads and then use these estimates in combination with runs for incremental, non residential lead intakes in the IEUBK model runs can drive potential differences in the magnitude of the resulting incremental increase in children's blood lead levels and distributions. These are further dependent on methodology when there is remediation of the residential but not those community lead sources that provide the Pb-B increment. The authors estimate incremental intakes of lead and any associated Pb-B increases by looking at the difference in the estimates for combined residential/baseline plus additional (non-baseline) intakes, minus the residential baseline. However, the pre-remediation incremental amount of Pb-B derived in this way (total intake - background) can be different from, and in fact lower than, the incremental amount that would be estimated post-residential remediation. The overall impact of incremental sources outside the child's home can be demonstrably attenuated, that is, underestimated in the modeling, when one looks only at combined significant intakes before any clean-up actions.

"The general biokinetic curve depicting Pb-B versus daily lead intake, or versus such other surrogate independent measures as level of lead in some medium such as soil, is curvilinear downward across a broad intake range (USEPA, 1986a, Ch. 10). As the intake increases, the relative incremental increase across the spectrum in Pb-B for an identical added intake becomes less and less. Because the model is constructed to reflect this curvilinearity, combining any high baseline lead intakes in the residential scenarios with an incremental intake, i.e., adding incremental lead intakes to those already far up the curve of Pb-B vs. Pb intake, would obviously underestimate what that incremental intake might produce in Pb-B if it had actually entered the simulations further down the curve of Pb-B versus total lead intake and in the steeper slope (more rectilinear) portion of the Pb-B vs. intake curve.

"What this means, in essence, is that one can't accurately quantify any residual risk to children after residences but not community lead sources are cleaned up if one estimates contributions of such lead to Pb-B by combining residential and non-residential contributions prior to remediation, especially if residence contamination is already significant. A more accurate depiction of that "incremental" contribution to Pb-B and therefore remaining child health risk after residential remediation would be provided by adding that lower range of soil leads likely to encompass any clean-up level for the residence to whatever the incremental lead intakes are.

"These comparisons can be depicted using several simple IEUBK runs for children 0-84 months of age. In runs with all parameters at default settings except the resulting soil and dust lead (using the default dust Pb = 0.7 x soil Pb), the incremental Pb intakes were entered via the alternate source setting and with a bioavailability of 30%. One can then compare the "% to exceed 10 µg/dl" using various simulations with and without incremental Pb intakes.

"For an incremental daily lead intake of 100 µg/d in both cases and using residential, baseline soils at either a pre-cleanup value of 2000 ppm or a value at 400 ppm which might lie within a clean-up range, there is a sizeable difference in "% to exceed 10" for children 0-84 mos. The high, baseline soil lead-associated Pb-B exceedence rate is increased only 12.3/100 children with a 100 µg/d increment, while the corresponding exceedence level at 400 ppm of baseline soil is 57.2%. That is, almost five-fold more children can be seen to exceed the 10 unit cut-off at the lower vs. the higher soil lead baseline. This is because the Pb-B vs. Pb intake curve is rectilinear and steeper at Pb intakes linked to a soil Pb value of 400 ppm than further up the curve, at 2000 ppm."

A second suggestion made by TRW that should be followed would be to use some sensitivity analysis runs for the various intake parameters, specifically the intake and the bioavailability runs, in the respective parts of Ch. 7.4.4., anywhere in pp. 7-39 et seq. These runs would be useful in resolving for the interested reader whether uncertainty in some model parameter is or is not a major matter. That is, critical comments from readers of the public draft may or may not be justified in critiquing uses of parameters that don't really make major impacts on the estimated Pb-B outputs, as G.M. values and/or distributions. To avoid hassles with new tables and figures, summary text describing sensitivity analysis inputs/results can be used.

II. C.A.R.T. Comments on the Public Draft HHRA.

It is my understanding that all of the C.A.R.T. comments are being collectively responded to by EPA Region 10's counsel and that I do not need to respond to these in any way.

III. Dr. R.M. Coomes/Basin Community Comments on the Public Draft HHRA

I offer both general and specific responses to Dr. Coomes' comments on the public draft of the HHRA. Based on his report's cover, Dr. Coomes represents the collective positions of various Panhandle Idaho communities in the Basin: City of Coeur d' Alene, City of Harrison, City of Post Falls, and Kootenai County, Idaho. Hereafter, these comments are headed as "Dr. Coomes."

IIIA. General Responses to Dr. Coomes' Comments

Overall, I found the general and detailed comments of Dr. Coomes to be a very mixed bag of criticisms. In some places within his submission, comments appeared to be appropriate or had at least superficial plausibility. However, in most of the other portions, his comments were confused and confusing, being quite vague and problematic as to their accuracy and comprehension in addressing many of the main issues. His comments were often misleading in terms of taking material out of context. For example, the geostatistical sampling minimum — seven versus ten — was covered in the HHRA, but Dr. Coomes' comments suggest that there is an unexplained inconsistency. He also drew distinctions among matters in the HHRA that appeared to pose little or no epidemiological or toxicological difference.

Especially troubling, he does not cite scientific underpinning for his criticisms and assertions, and no references are provided to back up his conclusions. This largely voids his comments where they run opposite to known science and history, owing to the real need for clear substantiation.

Dr. Coomes applies generalities to specifics inappropriately. For example, he cites a Science Advisory Board report from 1993 that purports to show that one can protect children adequately against non-cancer effects of contaminants such as those found in the Basin by using a child/adult lifetime exposure approach rather than those for children alone.

However, that report is misused by the commenter in that the approach advocated is only generally endorsed in certain situations. In the case of the Basin, there are exceptions that call into question applicability of that recommendation. Furthermore, SAB reports need to be updated with current science. No SAB report, nor any other report for that matter, is immutable over time. The SAB report being referred to is dated, in that we now know that for a number of contaminants that affect children and adults, in terms of non-cancer effects, little protection is afforded by using chronic adult "safe" exposures. For example, the recent 1999 NAS arsenic report notes that children are a population of likely higher vulnerability to arsenic's toxic effects. They cited examples of this.

Arsenic is a major contaminant of concern in the Basin, and these vulnerabilities are not captured in an adequate way by inclusion of the current RfD arsenic value of 0.3 ug/kg-day assumed for lifetime protection from lifetime exposures. I refer Dr. Coomes to recent research from South America that shows statistically significant in-utero, developmental adverse impacts of maternally-ingested arsenic on fetal development and early infant survival rates.

Ref. Hopenhayn-Rich C, Browning SR, Hertz-Picciotto I, Ferreccio C, Peralta C, Gibb H. Chronic arsenic exposure and risk of infant mortality in two areas of Chile. Environ. Health Perspect. 108: 667-773 (2000).

In the case of the main driver for risk assessment in the Basin, lead, children are scientifically and administratively the only focus. The case of mercury, which can be biomethylated in the aquatic compartment to produce the potent neurodevelopmental toxicant, methylmercury, is one where there is little or no protective margin in the RfD for developmental toxicity in fetuses and the early infant; nor would these age bands benefit from any reference to adult lifetime "safe" levels.

His comments are of questionable substance in other places. For example, seemingly trivial inconsistencies are cited in isolation as though they are determinative for risk. Finally, his comments include erroneous statements because they are uninformed as to basic technical issues and their correct interpretation.

Statistical Analysis Issues

Areas in Coomes' comments that are particularly misleading, vague as to precision and even seemingly uninformed are his multiple critiques about the various statistical analyses results and interpretations that form a significant end product in the draft HHRA. These include but are not limited to a cluster of comments in his Executive Summary (e.g., p. 2, p. 5) dealing with the various degrees of statistical associations for relationships among various parameters measured and processed in the draft HHRA, with particular reference to how one characterizes these associations and to what uses they are to be put. First, Dr. Coomes offers vague comments to bolster an assertion that if and when "correlations" were below 0.5 in the HHRA, they were not "significant." A comment also is made about a lower correlation coefficient offering poor "predictability." He goes on to say "...predicting or explaining one value in terms of the other is the goal of correlation coefficients," followed by "A correlation coefficient less than 0.5 means that at least fifty percent of the variability in the data cannot be accounted for in the analysis." Collectively, his comments on statistical issues as used here strike the informed reviewer as unfocused, confused as to terminology, and erroneous as to validity of application to risk characterization portions of the HHRA. Consequently, his comments often cannot be taken as valid criticisms of statistical analyses done in this HHRA.

A coefficient, especially a regression coefficient, for some inter-variable relationship in a large database with many variables and with many inclusions of controls for confounding variables can be numerically small but still be highly statistically significant. This is how one does statistical association analysis, testing for statistical significance level regardless of the value of the coefficient. There are examples of this in numerous articles on the environmental epidemiology of environmental contaminants, including metals, published in various open scientific journals. Those papers also make it clear that there is no magic number which an association has to reach or exceed in order to offer interpretive value. Secondly, it is not the case as he states that a “coefficient” less than 0.5 is not indicative of a "significant" association. Whether some value is or is not hinges not only on the level of statistical significance but also on the particular statistical design or statistical model being used.

For example, soil lead can impart its impact on lead on children's hands via various pathways, each having coefficients which depend on the model, e.g., the structural equation modeling approach for sorting out pathways. He indicates that a correlation coefficient (r) of 0.5 for an association means that 50% is unexplained and therefore the association is presumably meaningless for drawing inferences in this particular case of Basin lead contamination or other metal contamination. He apparently means the R-square statistic, i.e., explained variance via goodness-of-fit, not "r" per se. R^2 is the proportion of variance of the dependent variable y that can be directly explained by the variable x. Intrinsic in this, furthermore, is the overall existence of a regression line, not a simple correlation line. Dr. Coomes appears to invite the inference by the reader that other factors are therefore more important than lead. It is also curious that a number of the expressions of explained variance in the regression models that were used actually exceeded 50%. It's not even the case that all sections in the statistical results portion are at issue.

In the typical practice in epidemiological studies with complex biostatistical components, even very good associations in population studies can be less than "0.5", especially if the particular association being tested has been over-controlled for confounders that subsume within their controlling an environmental lead component. Anyone familiar with the environmental epidemiology of lead exposures of risk populations would know this. That is, if the remaining "0.5" has within it a basic association with the principal variable as well, then the crude association understates the overall contribution to the endpoint. Furthermore, the authors of the HHRA recognize in their statements on p. 6-21, Sec. 6.4.2, 3rd par. that explained variance in their Basin regression analyses are high for site studies of the type done in the Basin, and including earlier assessment of the BH communities "in the Box." The latter comparison is interesting since no one would deny that communities in the Box have their lead exposures clearly linked to the historical extractive industry lead contamination.

Dr. Coomes also seems to indicate his confusion about the difference between a correlation coefficient and a regression coefficient (see above my comments on the R-squared parameter). He states (see above quote) that predictions are the goal of correlation coefficients!! Correlation coefficients do not have predictive function; regression coefficients do. Many of the inferential statistical analyses carried out by the authors of the HHRA as well as by authors of the 1996 Idaho/ATSDR study have to do with regression analysis, including multi-regression analysis. For example, Sec. 6.4.1, pp. 6-20,6-21 in the HHRA sets forth some correlation matrices that have as their only purpose providing some crude idea of what associations are valid candidates for regression analysis. Sec. 6.4.2 deals with regression analyses themselves, the major analyses done for the HHRA draft report.

A regression coefficient from some regression analysis equation has predictive value, since the independent variable is clearly established in the empirical statistical relationship, thereby fixing the direction of a potentially causal relationship, and is expected to generally predict the dependent outcome for some value of the independent variable in any given set of circumstances. The size of the regression coefficient can be low and still have predictive value when there is statistical significance. The larger the study population and the larger the complexity of the study design, the higher the likelihood of more modest regression coefficients.

I refer Dr. Coomes to the various NHANES-type studies carried out over the years that include regression associations of lead in blood with such outcomes as systolic and diastolic blood pressure and blood biochemistry biomarkers of vasoactivity and kidney function. These regression coefficients seen in peer-reviewed reports from the NHANES databases are quite modest but significantly predictive. They are also universally accepted in the informed public health community as demonstrating a causal relationship for cardiovascular and cerebrovascular morbidity and mortality. As an added example, one can have a modest regression coefficient for a statistically significant effect on blood lead of lead intake from soil ingestion when applied in a regression analysis to hundreds of subjects in a human study population. We would also say that ingested lead from lead-contaminated soil causes elevated Pb-B; elevated Pb-B does not cause elevated soil lead. That is, the direction of potentially causal relationship when there is regression analysis of environmental lead as the independent variable in environmental epidemiological relationships is always unidirectional.

By contrast, a correlation coefficient has no predictive value since it merely depicts the relationship between two sets of data, neither of which need have a causal relationship to the other. Both sets can be viewed as being the "dependent" variable. Statisticians differentiate between the two by describing a regression relationship as being unsymmetrical and correlations as being symmetrical. That is, in regression analysis we observe the change in one variable as the other is permitted to change. For example, when a laboratory tests a new method for lead measurement, it is common practice to run results of the new method for a set of samples with data for the same samples using an established or "reference" method. Here, one derives a simple correlation coefficient, one which would have to be quite high in order to support adoption of the new methodology as being as accurate and precise as the method being used for reference. However, we don't say that the reference method has a potentially causal, independent relationship to the new method. The reference numbers say what they say as test results for any cluster of tested samples, and the method being tested likewise says what it says. How well the new method says what it in fact should say is assessed in the correlation analysis. A second correlation relationship example often encountered in lead epidemiology and toxicology is the level of lead in various experimental animal or human post-mortem tissues resulting from lead exposure. For example, lead exposure simultaneously elevates the levels of lead in both kidney and in liver, causing a significant correlation between kidney lead levels and liver lead levels. We do not speak of kidney lead causing liver lead or vice-versa. Nor do we say that the elevations track each other such that one closely "predicts" the other.

A persisting confusion between regression and correlation, cause and effect and basic mechanistic principles of lead exposure in risk populations appears to also occupy most of p. 5 of Dr. Coomes's Executive Summary. This portion dealt with modeled Pb-B levels, including a bizarre discussion of predicted vs. measured Pb-B levels. But it's not clear what the basis or the end result of his confusion is. The outcome seems to be that he holds any good agreement between modeled Pb-Bs via the IEUBK model and measured Pb-Bs as being due to chance. Making matters worse, he appears to have set up an irrelevant straw issue over the relationship of predicted versus measured Pb-B levels in terms of concordance and then proceeded to try to demolish that straw issue by saying there's no necessary cause-effect here by illustrating with an irrelevant example, the price of rum in Havana vs. salaries of ministers in Massachusetts.

This section of the Executive Summary is largely uninformed and meaningless to any serious dialogue between a reviewer and a reviewed work. No one is saying that there's anything more to the predicted vs. observed relationships than that compelled by known causative or other relationships between environmental lead intakes and predicted blood lead, especially when taken in tandem with causative relationships between environmental lead intakes and predicted blood lead. The set of source-pathway relationships to child exposure are depicted in Figure 6-6 in the draft HHRA.

There is an enormous global literature that is definitive and formed the basis of constructing the IEUBK model. This vast database compels a single conclusion of lead intake increasing blood lead, and arises from a huge literature for lead epidemiology in children, numerous compelling experimental animal results, and equally numerous biomolecular mechanistic studies showing lead to be a potent childhood poison, operating through its entry to and exit from blood. That is, these are toxic effects of lead exposure via lead intake from sources that operate through well-established dose-response relationships. I refer Dr. Coomes to any of many authoritative expert consensus documents, including the 1993 NAS/NRC study on lead exposure, the several CDC Statements on childhood lead poisoning, EPA's 4-volume compendium and peer-reviewed document, and the 1995 World Health Organization criteria document on inorganic lead. Lead sources produce lead exposure in children and this exposure manifests itself in various body compartments which not only lend themselves to measurement, e.g., Pb-B, but also show quite tight dose-response relationships to childhood toxicity.

The IEUBK model is called a mechanistic, biokinetic model for the simple reason that the model takes lead sources known to be significant contributors to child exposure and predictors of children's blood lead and processes them by in-vivo kinetic processes also well known in the open scientific literature. That is, when children are in a highly lead-contaminated setting, they will sustain lead exposure, with resulting elevation in a reliable biomarker for lead, Pb-B. One can assess this contribution of intake lead via various sources with a model or one can take measured blood lead levels and do inferential statistics to show what in fact these various sources and pathways contribute to Pb-B. Alternatively, by use of a well-validated model, one can input known sources and pathways of lead and generate Pb-B G.M.s and Pb-B distributions. The IEUBK model has been validated and has also been calibrated against a large number of site-specific applications. When we look for concordance between measured and modeled Pb-Bs for children at some Superfund or other site, we are likely not dealing with chance associations or spurious relationships. I find these particular comments of Coomes' in his ExSum to be quite remarkable.

Uses of Available Data With Reference to Their Diversity/Similarity

It is not clear that Dr. Coomes readily follows the uses of various lead-containing media for statistical analysis. In various paragraphs in the Executive Summary, for example, he repeatedly objects to the combining of data sets. This issue of combining data sets was heavily thrashed out in task group discussions as well as in the text of the HHRA. Again, it strikes me that either he has not read the document carefully or does not recognize answers to questions in his review already present in the HHRA. These criticisms do not merit serious response.

There are eight different areas identified for detailed assessment within the overall Basin, each of which was isolated for discrete statistical analyses. It is not true, as implied by Dr. Coomes, that the HHRA is trying to make a global statement about the Basin. The document makes it clear that there is considerable variability as to some parameters. That's why the HHRA deals with eight areas. In some cases, sediment/soil figured more heavily for typically defined soils, while in the Lower Basin there are no clear demarcations between what's sediment and what's soil. In addition, suspended or settled sediment under water is treated as an additional medium for lead exposure. So long as mixed soils and sediments have similar bioavailability, and intakes adjusted appropriately, it's not clear what the problem is.

Dr. Coomes' Comments on Sampling and Sampling Design Issues.

Dr. Coomes appears to misconstrue the caveats in EPA guidance for screening data not being permissible for baseline risk assessment with what's in the HHRA. What exactly does he mean, when we look at the criticism closely? Secondly, a number of the analyses in terms of their sampling geostatistical design were not, technically speaking, "screenings." That is, we are not uniformly dealing with screening-level data transformed somehow into more refined evaluations. There also seems to be some confusion underlying Dr. Coomes' comments as to what's a screening and what's a survey. He appears to refer to the expedited screening done for common-use areas. For example, EPA's RAGS, Vol. 1, HHEM, 1989, describes on pp. 4-20 the nature and valid uses of field screening analyses quite clearly and notes what is to be done to do further assessment.

He is also vague on the point of what are valid statistical analyses for data sets. For example, he notes on p. 2, ExSum that environmental dust data sets, i.e., 83 and 74 soil, mat, and house dust data points, are identified without apparent reason in the HHRA as not being amenable to statistical analysis. First, it's not clear what's precisely being referred to in terms of cited text of the HHRA. He may mean non-lead contaminants measured late in the 1996 to 1999 data pathway projects. The mat dust medium is itself a house dust contaminant measure, either as dust lead loading or dust lead concentration. The second measure is vacuum bag dust. The mat and vacuum bag dust is analyzed for lead in Sec. 6.4 in terms of concentration and lead loading, i.e., amount of lead per unit area measure. What is the discrete mention made of "dust" and how different from "mat" dust?

The HHRA makes ample use of statistical analyses for lead in dust pathways. I would note that, unlike lead, the soil-dust relationships for other contaminants occurring at sites is not well understood or characterized. Nor is Dr. Coomes accurate in implying that soil-dust contaminant relationships have been well studied at other sites in the case of non-lead metals and metalloids. They have not been. Some few other sites where this was attempted for arsenic, cadmium, etc. support the notion that we have a way to go for non-lead elements. One issue is that of standardizing what type of dust collection is appropriate. We have a good idea of what type is appropriate for lead.

Misstatements and Erroneous Statements

Examples of misstatements and erroneous statements by the commenter are present throughout the ExSum and the detailed comments. A good example is found in the ExSum discussion of samplings of, and on, the waste piles. First, there could not be a ready random selection of the waste piles within the entire Basin since they were heterogeneously distributed spatially and in terms of their relative accessibility to children. Those of the eight areas further up the Basin were more problematic for waste pile exposures. These especially included tailing ponds and waste piles such as those at Burke/Nine Mile.

Secondly, owing to apparent misreading of the general literature and EPA guidance on waste piles and specific assessment discussion of waste piles by HHRA authors, Dr. Coomes' comments are not tenable. First, EPA guidance would treat a waste pile as a "hot spot" for sampling assessment. Waste piles typically have the highest levels of lead and other contaminants when compared to other media. Such piles include waste in the form of tailings, weathered/weathering slags, disintegrating mine overburden, etc. EPA's 1989 RAGS document treats hot spots in a prescribed way. Hot spot discussions are contained in RAGS at pp. 4-10 to 4-12, 4-17, 4-19, 5-27, 6-24 and 6-28. On p. 6-28, last par., left column:

"In some cases, contamination may be unevenly distributed across a site, resulting in hot spots (areas of high contamination relative to other areas of the site). If a hot spot is located near an area which, because of site or population characteristics, is visited or used more frequently, exposure to the hot spot should be assessed separately."

This says that assessment is to be site-specific and focused on the specifics of the interactions occurring between human receptors and the waste pile. Furthermore, one does not merely test the top inch or so of material at an extractive industry waste pile. There is a simple reason for this, but one that appears to have escaped the commenter. That is, children who are infants and toddlers will only typically encounter the surface of contaminated materials, such as their home play area soils. With waste piles, we don't have infants and toddlers crawling up, over and down waste pile surfaces and engaging in mouthing activity. Even somewhat older children are not interacting with waste piles in this behavioral fashion. What we have are older, mobile children interacting with waste piles in diverse ways, such as peddling their bikes on the piles, running up and down and, thereby breaking through the surface and contacting deeper strata in doing so. They would likely take their pets with them, providing another recognized vehicle for picking up waste particles at varying depth. The HHRA was correct in taking into account deeper sampling depths for piles, although its reasons for doing so differ from the above rationale.

IIIB. Specific Responses to Dr. Coomes' Comments

Executive Summary

p. 1, par. 1 This comment in the last sentence is too vague to respond to. The HHRA draft makes it clear that there is a bit of a structural distinction between CSM models 1-5 and the eight areas in the Basin selected because of human vs. ecological impact. However, as noted throughout early parts of the HHRA, the rationale for overlays of FSAP protocols with the CSMs do not actually make it difficult to merge the two approaches. Given the vagueness of the comment, and its marginal value even if clarified, it ought to be minimally responded to or not accepted.

Ibid., par. 2 Again, too much ambiguity to be useful for response or to be a candidate for acceptance. What exactly in the FSAPs or the early parts of the HHRA dealing with data sets selected for the HHRA refer to the inadvisability of combining data? He does not elaborate. The topic area Dr. Coomes refers to is really that of multimedia exposures, and multimedia exposures that reflect the highest likelihood of occurrence for the most vulnerable child receptor away from the residence, i.e., the more mobile child, 4-11 years old. The 4-11-year-old child is still into oral exploratory behavior at the younger end of the range, 4 and 5 years old, so as to consider soil surface contact with contaminant levels but mobile enough at the older age end of the age band to show significant contact with sediment. How does Dr. Coomes make his point averring that the data for sediment vs. upland soil were not meant to be combined??

Ibid., par. 3 This paragraph can be rejected as a non-relevant criticism as to variability of contamination in the Basin somehow being such that one can't do Basin assessment. The commenter ignores the fact that the Basin was specifically divided into eight areal segments to minimize any problems of excessive heterogeneity frustrating geostatistical and exposure analyses. The problem was recognized and dealt with by the authors and the HHRA team before Dr. Coomes was provided a copy.

Ibid., par. 4 plus carryover, p. 2. This criticism is misleading or what EPA says is misunderstood in terms of EPA RAGS guidance. It is not valid and needs no response of any substance. See the previous example on this very matter in the above general comments. What's more, it's not clear that in every case, field "screenings," even when confused with Basin surveys as occurred here with Dr. Coomes' interpretation, automatically require prescribed added assessment. The actual nature of the samplings and their statistical nature determine what, if anything further, needs to be done to do a "baseline risk assessment."

p. 2, 1st full par. This comment was dealt with as an example in my general response provided earlier. In light of that response, and given any citation for which SAB report he could possibly be referring to, the comment requires rejection with my explanation provided.

Ibid, 2nd par. This can arguably be rejected. I note responses to this in my earlier general responses.

Ibid, 3rd par. This par. has a number of confused and confusing, seemingly erroneous, statements. There's little to respond to and it cannot be accepted. See my multiple responses above in the general responses.

Ibid, 4th, 5th par. Cannot be accepted for reasons given already in my general responses.

Ibid, last par. & onto p. 3, top It is my interpretation of the eight different areas that the residential, baseline scenario for the segment is for baseline, not incremental, scenarios. Construction workers would fall under the latter. Dr. Coomes may have some problem with what's residential and what's incremental in each of the eight areas. Response to this by the HHRA authors should clarify the distinction to prevent any confusion.

p. 3, 1st full par. This comment is not tenable owing to ambiguity and unsubstantiated evidence for the seasonal band April through November being too broad. The authors may wish to emphasize the range in temperature and other climate conditions that justify the number of months selected for minimal-clothing, dermal exposures.

Ibid, par. 2 I really don't understand this comment. It would be difficult to respond to, since its point is unclear. The exposure point concentrations and the applicability of these values for the different clearly identified risk groups are spelled out as to specific areas in terms of both current and plausible future activity or future site use scenarios. The HHRA in several sections of Ch. 5 and such parts of Ch. 6 as Sec. 6.5 estimates, via multiple tables, various scenario lead and non-lead levels. For example, Dr. Coomes seems to believe that if there's no current construction activity going on in any of the eight areal segments in the Basin for assessment of residential/neighborhood baseline and incremental occupational scenarios then they should not be included. I see in this par. a misunderstanding of a baseline HHRA as being open-ended as to time frames. That is, future scenarios as well as current ones are the purpose of the HHRA.

Ibid, Par. 3 I suggest that the authors of the HHRA consider what he is claiming and they respond to it. Something does not make sense here. For one thing, are these in reference to the lead, non-lead, or both portions as captured in Ch. 3 and later sections?

Ibid, last par. & follow on to p. 4 The comment is quite vague as to what is its meaning for contaminant frequency of exposure. Of course, every time a young child or even older child mouths his fingers or otherwise ingests soil, there would be dermal contact preceding ingestion. However, this is not what one quantifies in dermal exposure. The small surface area of the child's hands and the histological composition of finger/palm epidermis makes applicability of dermal exposure here of little consequence. Dermal exposures can occur more frequently than soil ingestion within the meaning of both the exposure factors recommendations of EPA in its Exposure Factors Handbook, 1997 version, and the various scenarios for contact in the three settings identified by Dr. Coomes. Dermal exposure in swimming is higher and more frequent as to occurrence in those older receptors where the frequency of actual incidental ingestion of soil is inverse, i.e., dermal exposures for a number of activities occur more frequently and involve more body surface area with age and less mouthing or incidental ingestion.

p. 4, 1st full par. This par. does not require acceptance because its premise is flawed. In the sections in Ch. 4 and Ch. 5 dealing with arsenic, for example, there is a discussion of the range of cancer risks as a preliminary cancer risk goal as well as some discussion of how high an individual estimate within that range need be before remediation. More to the point for a contaminant like arsenic with well-documented skin and internal cancer risks and with wide acceptance in regulatory quarters nationally and internationally as a very potent carcinogen in human populations, the notion that a risk less than E-4 does not require serious consideration for remediation action is a misstatement of EPA guidance and recommendations to risk managers.

Ibid, 2nd par. This par. so grossly misstates what the uses and limits of the IEUBK model are generally and for use by the authors of the HHRA that it cannot be seriously responded to. First, intermittent exposures of sufficient time to allow operation of steady-state lead kinetics in-vivo can be handled by the model. Intermittent exposures in the context used in the HHRA does not mean we are speaking here of acute exposures of a day or a week or so. Dr. Coomes is confusing acute exposures of several days or weeks with exposures that can be both intermittent but of sufficient length in those intermittent occurrences that they obey the requirement for steady-state kinetics to apply: for example, recreational exposures occurring in warmer seasons. That is, exposure is long enough for use of the IEUBK model even though unceasing, chronic exposure may not be occurring. I refer Dr. Coomes to the comments made by the TRW for lead, which I think will appear eventually as part of an Addendum to the public draft.

Ibid, 3rd. par. I can't respond to this since it is not clear precisely what he is referring to. Are the two day groups in reference to the lead and non-lead portions of the exposure factors sections in the HHRA? The IEUBK model selection of time intervals was clearly spelled out in the portion of Ch. 6 dealing with predicted children's and worker/adult Pb-B values.

Ibid, last par. Dr. Coomes seems to be setting up a straw issue here in terms of rigid protocols for DQOs and actual uses of data in a any particular risk assessment. This issue appeared to be addressed adequately for lead and non-lead sampling portions as applied to a BRA. I leave this particular matter to URS and TG data analysts to address the specifics of the three bullets as given in this par.

p. 5, all This page does not merit acceptance, because of its flaws of fact and interpretation of the huge database. A comprehensive response was provided to this criticism and its highly problematic nature in my earlier comments dealing with statistical analysis issues. That rebuttal also provided comments on the matter of what predicted Pb-B values using biokinetic models mean.

Responses to Dr. Coomes' Detailed Comments

p. 6 , first par. Dr. Coomes seems to have overlooked the fact that the CSMs were simply included for comparison purposes with the eight discrete demographic study areas within the Basin. This was not hard to do, and I in fact noted in a number of earlier review comments that outside readers will get things mixed up. That appears to have happened here. While the CSMs were developed for ecological assessments, this would not materially impact the HHRA since this HHRA focuses on the eight discrete demographic segments. One can simply read the HHRA's chapters and see that the entire assessment is done on the eight areas occupied by some level of human activity. It is not driven by theoretical constraints arising from original depictions of the CSMs. The latter do not even appear in the numerous tables and figures in the risk assessment portions of this HHRA. The criticism can be rejected as irrelevant.

Ibid, 1st bullet. It is not clear that this comment can be accepted as it was stated and as it would typically be interpreted. The first bullet presumes on the definition of chronicity of exposure in the EFH as applying here and also whether adjustment or normalizing for total seasonal or annual time exposures was factored into Dr. Coomes' critique or not. I do not believe the commenter has accurately characterized what went into coming up with the final daily times adjusted accordingly. The authors should, in their own responses to Coomes, spell out a repeat of the rationale and assumptions going into the time intervals of exposure.

Ibid, 2nd bullet. This comment is even murkier than the first bullet above. Somehow, we are to conclude from a sign and some vague assertion of available "evidence" that there is current use. Again, it is not a necessary condition that there be actual present use, but that there can be use. Secondly, I don't see what's offered as substantiation for the criticism that it is tenable. The HHRA authors can respond as they wish in terms of accepting part of the comments.

p. 7, 1st full par. There is nothing in the 1989 RAGS document on field screening efforts that would say that the survey data for all but the expedited area is even at issue. As to the expedited screening level assessment for this one segment of the Basin, I leave it to the HHRA's URS-Greiner contractor authors, who would be clearly acting within EPA Region 10 guidance, as to whether the amount of exposure that needed to be "modified" was so substantially different from what was done that it required further assessment before any inclusion in the HHRA.

p. 7, bullet, Ch. 3 I have already responded to Dr. Coomes comment in the ExSum about SAB endorsement of using a combination child/adult approach. As I noted, this approach does not really provide protection from developmental effects of arsenic. In addition, there are concerns about neurobehavioral effects of As being more pronounced in childhood exposure.

p. 8, 1st bullet Sec. 3.2.2. only has a short paragraph on dermal uptake of COPCs, including a general statement on use of soluble vs. insoluble/partially insoluble substances and the statement that the tap water and surface water routes were not quantified in the HHRA. Dr. Coomes grossly misstates this short paragraph as "extensive discussion." He also misstates significance of the paragraph. That is, since no quantification occurred even though this pathway was a complete one, it is difficult to see any relevance to the remark or the usefulness of any required reconciliation with other sections.

Ibid, 2nd bullet He's correct in noting a cross-reference in error. The section at issue is 2.4.5, p. 2-17, subsection on Air, bottom of page.

Ibid, 3rd bullet. Dr. Coomes states that the HHRA deals with dermal absorption of metals as being more significant than stated in Sec. 3.2.3. Section 3.2.3 is correct as written. He does not identify what exactly is inconsistent with 3.2.3 text. The other sections on dermal exposures do provide details on dermal uptake, but it's not indicated that dermal uptake vs., say, oral ingestion, would be a major route. HHRA authors will wish to deal with this. I don't find the criticism substantiated and requiring acceptance.

Ibid, 4th bullet I thought the HHRA dealt with any inconsistencies with minimal samples to be taken for geostatistical adequacy in terms of confidence limits and representativeness. I leave response to the URS-Greiner contractor authors and Region 10 to sort out.

Ibid, last bullet See my general comments dealing with this issue. Again, it's not clear that the commenter is up on the literature for soil-dust relationships and those limitations for non-lead contaminants.

p. 9, 1st bullet It's not at all clear to me from what the HHRA says about uncertainty between yard soil and house dust, or from what the actual statistical analysis methods being used in the regression results in the HHRA indicate, that one has to use nonparametric testings to resolve uncertainty and variability. It is also not the case that nonparametric techniques are equal to the task for two data sets with complex association(s). The commenter recommends the Wilcoxon Rank Sum (WRS) non parametric test, basically equivalent to the Mann-Whitney (U) test. In fact, in his comment submission, he encloses such an analysis. The WRS is a nonparametric analogue of the t test for two independent sets of samples wherein one simply replaces actual measurement values with rank scores. This has the virtue, like all nonparametric approaches, of not shoehorning data into an assumption of normality to the distribution. It does, however, assume that both data sets have the same underlying distribution.

If one does so, however, one encounters limitations for the dust contaminant-soil contaminant relationship. In more complex statistical relationships, nonparametric testing becomes less efficient and less useful. What's more, the type of test suggested by the commenter is, like other nonparametric tests, mainly probing significance and not elaboration of confidence limits. Put differently, one does not resolve uncertainty in statistical relationships by using a quick-and-dirty nonparametric significance test that hides more uncertainty than it reveals.

I also believe he has mischaracterized what the HHRA is saying about variability and uncertainty in the soil-dust relationships across the eight areas. For example, the very dusty conditions at Burke/Nine Mile were recognized as possibly spelling somewhat different robustness of relationship than in others of the eight subareas. Also, the role of housing age and the level of severe deterioration were ascertained and the relative contribution of deterioration in lead-painted surfaces across the eight areas will affect the nature of distribution of dust lead vs. soil lead values. However, these area-specific differences have been examined for each of the areas.

Ibid, 2nd bullet The first sentence does not make any sense, and at best is a mischaracterization. Is he saying that it is somehow only because of uncertainty bounds in the analyses that the relationship of soil to dust becomes significant? And who is he saying has concluded this, he or the authors?? He then moves on to uncertainty as defined by EPA guidance. The detailed uncertainty discussion in Ch. 7 for both lead and non-lead contaminants seems to have been ignored. Based on vagueness and irrelevance, I would not accept the point of the statements, even when they are translated.

Ibid, 3rd bullet I agree that the term "exact" is misleading and in any event inappropriate. I would suggest deleting "exact" and substitute with "adequately characterizable" or similar wording.

Ibid, last bullet with carryover, top p. 10 This comment can be dismissed. I have rebutted it in my general comments above and the statements can be referred to.

p. 10, full bullet This is really a matter for URS-Greiner and TerraGraphics to respond to, as to details of sampling plans and QA/QC.

p. 11, to top of p. 12 The commenter seems to accord EPA guidance the status of compulsory adherence and to require cookbook approaches to any and all risk assessments without any professional judgment. That's not true! Whether stirring or not stirring sediment into a water column has prescriptive information in EPA guidance or not, it is a path of human exposure that makes quite good sense for the beach setting identified and the application of professional judgment. EPA does not hold out its guidance to be always inclusive of each and every conceivable exposure pathway scenario under the sun and applicable forever. Second, what EPA does or does not consider the "same" site is not defined by either EPA or the commenter for each and every possible pairing of samplings.

Dr. Coomes seems to be offering a booby trap, but a largely visible one. That is, he holds that EPA says that one has to sample something called the same site for all components of that mixed medium. However, if you do that, you are then overcounting. First, the mechanism for exposure to any intact sediment has little to do with orally ingested sediment particles in suspensions encountered by someone, say, wading and swimming in an area where a number of individuals are stirring up the water and where suspended particles become laterally mobile, especially for riparian or lateral lake beaches. The respective contact areal spreads are not identical. I considered the respective discussions in the HHRA on the above points to have been reasonably differentiating.

p. 12, 1st full bullet Dr. Coomes takes issue with the wording. He also asserts one cannot simply change the wording to solve the matter. How so, pray tell? Unless Dr. Coomes knows exactly what the authors meant in statistical terms as to what is their worst case, he can't second-guess whether one can revise or not. This comment is meaningless. I assume the original statement was more under the statistical rubric of a 95%-RME scenario, in which case worst case would be ambiguous. I leave it to the authors who drafted this portion to refine what they actually meant.

p. 12, 2nd bullet Dr. Coomes' caveat seems to have surface plausibility in the case where construction activities are simply confined to a highly localized intrusion into otherwise undisturbed topographical features within the Basin. But other scenarios apply as well. I see some virtue in clarifying this text on p. 3-41 to respond to his concerns.

p. 12, 3rd bullet Dr. Coomes is concerned that while the small sampling may be o.k. for the residential baseline scenario, how does one characterize construction activity? I have several responses to that, but I will defer to the authors to respond as to the extent to which the actual likely construction areas in the Lower Basin are handled by the sampling data already in hand.

p. 12, last bullet I am not sure this quantity could be correct??? Without digging into the EFH in its 1997 update, the indicated average value of 71.8 kg for men and women versus the conventional ICRP Reference Man handbook values, with its 70 kg male adult and 50 kg female adult (for an average body mass of 60 kg) could not have changed that much. This figure should be checked for accuracy by the authors.

p. 13, 1st bullet The commenter takes exception to the time allocated for worker exposures. I don't see the stretch being made by him between the loss of population and any decreases in construction time. First, the loss in population is not equally distributed socioeconomically or demographically. Unless he can say that population trends affect that segment of likely future construction workers, then I see no merit. In fact, with the specific case of long-term, large-scale soil and other remediation efforts in the Basin having to draw on fewer workers, then by Coomes' logic, the exposure times would greatly increase, not decrease.

Ibid, 2nd bullet This is silly nitpicking on the part of Dr. Coomes, and is based on unfounded speculation offered in rebuttal about what people inadvertently ingest as water. I would ignore the comment. A volume of 30 ccs is a bit over an ounce of water or one-sixteenth of what a child splashes at another, i.e., a pint. This amount could easily and reasonably be imbibed with water play and vigorous splashing among children, and hardly requires submersion behavior for much of that hour.

Ibid, 3rd bullet Like the previous bullet, there is only undocumented speculation as to how cold ambient conditions get up and down the Basin on a monthly basis. The inference Dr. Coomes wishes to be drawn by the reader would be that kids would be tearing up bare feet on ice, not to mention one could never go about without being bundled up. I find it hard to accept this fanciful, if evocative, problem of kids freezing from April through November. What has Dr. Coomes evaluated among weather data and climatological distributions seasonally to make that kind of statement?

Ibid, 4th bullet Again, there is unfounded speculation about what would happen with particles adhering to skin post-beach play. Maybe people will be in the water, maybe they won't. The HHRA had to anticipate likely activities for all receptors collectively, but one cannot say that some specific receptor engages in the same activities as all others. I do not find an adherence factor of 0.2 to be excessively protective in a risk assessment. For example, for the young infant, playing in beach waterline sediment/dry beach soil, the level of skin contact vs. body skin area contacting these media would be much higher than for older children, since the infant remains out of the water and involves more of his/her body surface area with medium contact.

Adherence is a function of particle size as well. To say 0.2 adherence is excessive is to say that not only will the particles not remain for any time, but that the fraction of small, adherable particles is less than 20% of the particle distribution, i.e., <20% with particles < 250 microns. This is not convincing.

Ibid, 5th bullet I agree here with Dr. Coomes. The actual percentile can be stated. The text already indicates that one can ingest up to that amount, so one might be led to believe that this %-ile is more like 99% than 95%.

Ibid, last bullet with carryover to p. 14 Dr. Coomes misrepresents or misstates what the relevance of the OSHA Pb-B limit is to protecting workers at brownfield sites. I believe Region X needs to be the main responder here. The practice of employers has been to remove women from the worksite as soon as they are known to be pregnant. Until the U.S. Supreme Court weighed in, in the Johnson Controls case in the early 1990s, it was assumed that pregnancy per se was the "medical removal" trigger, not some Pb-B value. Nor does OSHA have a direct conflict with EPA practice via its adult model for setting PRGs. EPA is exercising its area of legal authority. Dr. Coomes is referred to the 1996 document on the development, uses, and context for the adult Pb model when applied to worksite women of child-bearing age.

pp. 14-15 Dr. Coomes offers an unsubstantiated set of comments about his general problem or problems with the definitions and characterizations used for setting the exposure areas for the various receptors. For example, for children 4-11 years old, he notes that movement more than two miles from the residence is unlikely. What is his evidence for this? He repeatedly attempts to rebut risk parameters in this HHRA with undocumented speculations as to what is "likely" or "unlikely", or more appropriate, etc. This HHRA is not a dartboard for Dr. Coomes to toss a speculation wherever he wishes. I am inclined to ignore these many bullets focused primarily on dissecting and challenging the exposure factors portion of the HHRA. He offers little technical published material to support the comments.

p.15, Future Land Use This has little credence. It is not at all clear how current declines in one subset of the population, one among a number of risk populations, would materially color future land use considerations. The HHRA, furthermore, notes that the rate of decline has attenuated. What's more, there appears to be a potential in-migration of the more high-risk segments of the child population: that is, those of low socioeconomic status and those also unaware of the extent of the exposure problems. The discussion in the commenter's submittal on the matter of groundwater seemed unfocused and, what's more, unsubstantiated. What evidence does Dr. Coomes have that there would be zero likelihood of side canyon development? The authors can weigh in here.

pp. 15 to 16, CSMs, 3-3 to 3-11 It seems that Dr. Coomes is unclear as to the fact that the CSM maps are provided for completeness, the populated areas within the eight geographic segments of the Basin being the spatial, demographic and environmental discriminator. The comments here reinforce my concern noted in several internal reviews that the overlapping of CSMs and geographic areas would create considerable confusion. The authors may wish to reinforce the relative status of the eight areas vs. the CSMs in the various maps in Ch. 3.

p. 16, Tables Ditto in the large table, Table 3.19, for comments offered above for CSM figures. Authors can respond as they wish. The authors also can respond to comments on Table 3-21.

Ibid, Comments on Table 3-22 The commenter has a point regarding how the frequency of tap water drinking would be different for any other residence-based exposure frequency as presently presented for CT and 95%-RME in Table 3-22. This should be clarified by the URS-Greiner and TG authors. As presented now, it appears tap water intake CT frequency is only 90%, 234 d/y, of the yard soil CT frequency, 260 d/y.

Ibid, last par. on age-based water intake rates The commenter is simply wrong about there being uniformity of water intake rates in children vs. adults. Children are well and widely known to consume water at a higher rate per some anthropometric value compared to adults. They therefore consume contaminants at a higher rate, regardless of how water needs are indexed. The caloric requirement per unit body weight is higher than adults, and water intake is linked to caloric requirements and physical activity. Generation of more water intake is also indicated by ventilation rate and oxygen intake requirements. Whatever the metric, kids have a higher water requirement.

I refer Dr. Coomes to the paper by Calderon and colleagues in a 1999 EHP article dealing with age-based water intakes in the U.S. and, because of this, increased arsenic intakes in children as a function of body mass. It shows U.S. children consume much more water than adults on a body mass basis.

Ref:

Calderon RL, Hudgens E, Le XC, Schreinmachers, Thomas DJ. Excretion of arsenic in urine as a function of exposure to arsenic in drinking water. Environ. Health Perspect. 107: 663-667 (1999).

I also refer Dr. Coomes to the EPA ODW/OGW 6/22/00 Federal Register notice [[65(121) FR 38888, 2000]], on proposed As MCL rulemaking, which includes statements that the early, bottle-feeding infant age band is a clear risk group for arsenic is because of the high daily water volume intake per body mass. These two citations and many others, such as the 1984 EPA health assessment document for arsenic, show that there is an inverse relationship between water volume intake and unit body index, e.g., kg body mass, such that the younger the individual, the higher the intake rate.

p. 18, Tables 3-23, 3-24 I responded to these issues earlier and one can refer to what's noted there.

Ibid, Sec. 5.0 comments on cancer risks for non-lead contaminants I have already responded to this assertion by the commenter and the responses can be found above.

p. 19, Section 6.0, 1st par. This concern about what is or is not intermittent exposure has already been addressed by me. See above general comments.

Ibid, Sec. 6.0, par. 2 onto p. 20 Dr. Coomes clearly is not aware that OSWER guidance for use of the IEUBK model does permit breaking out exposure modeling into, first, the residential unit and then incremental exposures. That is the whole basis of the uses of the IEUBK model in the HHRA and for the eight Basin areas. I refer Dr. Coomes to the OSWER directives on uses of the IEUBK model appearing in 1994 and with a confirmation of proper uses in August 1998.

p. 20, 1st full par. The HHRA authors should double check Dr. Coomes' calculations here to ascertain accuracy.

Ibid, Statistical Correlation I have already addressed the multiple flaws in Dr. Coomes' comments about statistical analyses in the general comments above.

p. 22, top, Summary Baseline... The rationale for use of the 4-year-old child can be provided by the authors. The HHRA authors can also address the following three bullets. The commenter statements are basically computational or editorial fine-tuning.

pp. 22-23, Recommendations I leave responses to recommendations to the authors, since the recommendations involve Coomes' views about what needs revising.

Dr. Coomes' Figures and Tables As I read these submissions, they can be easily addressed by the URS-Greiner and TG authors. I would note, however, several technical responses. First, the correlations between As and Pb, when we take into account the fact that these two elements can have differing vertical migration rates in soil over time, and that associations between elements presupposes some stability to the soil/sediment strata over time, appear convincing as to having the same geochemical emission origin. What's more, there is nothing in the Basin that would comprise an alternative source for As. As is not in interior or exterior paint, and there is no historical support for its use as an agrichemical in the Basin, etc. However, As is a common co-occurring element in extractive industry wastes.

Disturbances in surface soil strata from one geographical area to another and alterations that intrude to various depths, and have impacts with respect to various correlations, are understandable. They have some variability as to the degree of soil surface disturbance over the decades. Simple logic says that areas within the Basin that have more residential density or any agricultural uses over the decades will reflect different depth-linked ratios and concentrations than those minimally disturbed by various anthropogenic activities.

PB Associates

Memorandum

From: Paul Mushak

To: Sharon Quiring, Sean Sheldrake, Marc Stifelman, Ian von LIndern

Date: 12/15/00

Re: Part 2, Response to Public Comments

Part 2: Responses to Public Comments on the Draft HHRA

Paul Mushak, Ph.D.

I have general and specific responses to submissions for public comments on the draft HHRA. These comprise Part 2 of my responses, Part 1 having been submitted earlier, and address comments from the Shoshone Natural Resource Coalition (hereafter SNRC), the Lands Council, and the Coeur d' Alene Chamber of Commerce (hereafter CDACC).

IV. SNRC Comments

General and Specific Responses

The SNRC offers five general items, within which are a number of specific comments on the draft HHRA.

Item 1 The comments here are really more to the issue of views of economic development and the validity of different approaches to handling clean-ups in the Basin. As such, they are beyond the scope of the HHRA, its authors, or its advisors.

Item 2. Comments on Summary and Conclusions, p. 8-5 The set of questions indicates that the SNRC sees answers to its bullet questions about various sources of lead, especially amounts of paint lead vs. extractive industry lead being most hazardous to children. That is, those children requiring intervention should be looked at with reference to what's the most pressing source of child lead exposure. While these questions have plausible surface purpose, they ignore the simple fact that the nature of the health intervention program does not permit one to draw broad conclusions about the Basin itself. The sample size, N=50, is too small for meaningful statistical analysis, and the nature of the children being evaluated

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did not lend itself to specific inferential statistical analysis techniques. In brief, whatever the association of housing age or soil-dust lead specifics with the 50 children, it is not technically permissible to use any attempted analyses and draw Basin-wide conclusions. Such conclusions would be meaningless for the Basin.

Item 3. Comments on Risk Factors. The comments in Item 3 seem to indicate that the risk factors mentioned in the Item somehow get lead off the hook because it is purportedly those factors, not lead contamination, causing the problem. The comments have it backwards. Simply put, when there are risk factors that enhance lead exposure/poisoning problems in a community, there is every reason to take even more pains to minimize risks to child health by minimizing the extent of lead exposure by adequate lead remediation.

The commenters have a problem with use of a simple HHRA model to seemingly over-involve yard soil lead vs. other Pb sources. What's more, this is all foregone, in their view. The principal mode of assessing risk in the Basin is that dictated by EPA OSWER guidance, to not only attenuate the kind of questions arising with survey Pb-B data representativeness, but also open-ended applications for any future scenario. The authors of these comments appear to be unclear in their own minds as to what is the best approach for assessing risk, and the best approach for risk assessment that helps risk managers taking the long view.

In addition, the letter writer misstates what went on in the HHRA. The HHRA used yard baseline scenarios combined with incremental risks from non-residential exposures. This comment was selective and based on things taken out of context.

Item 4. Blood Lead Assessments The comments about the Panhandle Health Dept. screening efforts don't make much sense. All children should be screened in August, whether they are tested by PHD or not. The PHD assessment is for a specific purpose, which is a valid one. However, other studies such as the 1996 ATSDR/State study are more representative. What's more, one can make the argument that screenings and surveys in the Basin can either under-represent or over-represent risk. The contributors to bias in the Pb-B results were reasonably well handled in the draft HHRA ExSum and Ch. 8 Summary and Conclusions.

Item 5. Excessive Use of Safety Factors Item 5 first presents five bullets that collectively argue that the HHRA has seemingly built in over-protection, i.e., too many safety factors. That is not true, nor are the criticisms relevant. The criticisms show considerable ignorance about widely accepted environmental epidemiological and toxicological aspects of lead.

Bullet 1 seems to take exception to using August sampling to maximize survey data. That's more than a bit silly. We know from an extensive, widely accepted scientific and clinical literature that it is important to be able to monitor maximum Pb-B values, not values less than maximum that occur in other seasons. Why? Because dose-response relationships for lead exposure and lead poisoning are based on the concentration of Pb-B achieved, so that the maximum toxicity risk in exposed children is only validly ascertainable by testing when Pb-B is at the maximum.

If the point of the criticism is that Pb-B values are lower and there is therefore less risk at other times of the year, the logic is meaningless. We do not know mechanistically what is the minimal time period for children at some maximum August Pb-B value to sustain toxic harm. A maximum Pb-B achieved for several summer months would be assumed to be sufficient to produce maximal harm. Secondly, neurodevelopmental harm in children is irreversible. Harm produced in August at maximum Pb-B value does not reverse at lower Pb-B values in other seasons. Simply put, one cannot average out Pb-B values throughout all seasons and use that in a dose-response relationship. That's simply not how it works.

Bullet 2 asserts that high-end ingestion rates were used for all scenarios. This is hardly the case. Based on current information about how much soil and dust children ingest, including recent and ongoing studies of Calabrese and Stanek, the values chosen in the HHRA are not all at RMEs. See for example, the newly-published paper by these authors in the October Risk Analysis:

Ref: Stanek EJ, Calabrese EJ. Daily soil ingestion rates for children at a Superfund site. Risk Analysis 20: 627-635 (2000).

They are likely somewhere between CT and 95%-RME values.

Bullet 3. This point of this statement is erroneous, or at best, misleading. The whole fish scenario is applicable for traditional subsistence practices of the CdA Tribe in the Basin. Whole fish describe the traditional dietary habit of these people. They did not fillet fish like the Eurocentric settlers or current residents.

Bullet 4. This point about using shallow well scenarios is ambiguous. Relative to deep wells, shallow wells invariably carry a higher contamination or likelihood of this. I don't believe the HHRA indicated anything more than this in the use of shallow-well groundwater exposures.

Bullet 5. EPA can respond to how the adult modeling assumptions for contaminated soil workplace settings jibe with the OSHA value and what is the legal basis for use of 10 μg/dl as the LOC. Secondly, the comment confuses a long-obsolete standard that is woefully out of date with current accepted science for fetal dose-toxic response relationships. What's more, the numerical value has often been bypassed by the practice of removing women from the exposure setting when pregnancy occurs, at least subject to challenge under the U.S. Supreme Court ruling in the Johnson Controls case in 1991. As noted in many expert consensus documents of public agencies, such as the 1993 NAS/NRC report on sensitive population lead exposures, maternal Pb-B values at 10 units or even less are linked to threats to fetal development.

Bullet 6. The points about waste piles mischaracterize the approaches for dealing with waste piles. First, the way children interact with waste piles means that various depths of piles produce exposures. Older children, especially, encounter waste piles at potentially diverse depths: surface and subsurface. Secondly, these waste piles have the highest levels of contaminants of all media encountered by Basin children. Therefore, there are more negative consequences for child protection with any failure to be adequately protective with exposure factor assumptions. Underestimating intakes of fine tailing particles that contain 10,000-20,000 ppm lead, for example, can have great consequences in terms of toxic harm. I refer the commenters to my responses to Dr. Coomes on this very topic.

The commenters are correct that 25% was the best outcome. However, the comment is misleading in that the ExSum makes clear that the level of participation can either underestimate or overestimate best likely estimate of Basin-wide exposures. It is incorrect to assume or assert that the level of participation as occurred would only have somehow overestimated risk. The opposite could have occurred.

The last comment on p. 2 shows a total unawareness of the nature of blood lead measurements, the role of the IEUBK model at waste sites, and the interplay between the two. Commenters are referred to the August 1998 EPA OSWER directive on these matters. That should clarify any confusion.

The first paragraph, p. 3, is contradictory on its face and circular as to its logic. The only evidence that the SNRC or anyone else has to show how safe or unsafe the Basin is, is the HHRA. The commenters offer nothing equivalent to the HHRA to rebut the HHRA. Until that appears on the scene, the current HHRA is it.

The last paragraph challenges the HHRA to look beyond the "status quo." In point of fact, looking beyond the status quo, i.e., looking beyond current status of exposure, is the rationale behind agencies in general and the HHRA in particular using the IEUBK model for risk characterization for lead to anticipate future-use scenarios as well as current exposure settings, i.e., the "status quo."

V. Lands Council Comments

The Council comments generally support the draft HHRA. The Council, however, does advocate use of the more conservative default model versions vs. the Box model. The selection eventually becomes a risk management issue, which is where a number of the Council comments of this nature need to be directed at some future point.

VI. Coeur d'Alene Chamber of Commerce Comments

The Chamber of Commerce (C of C) comments are highly focused and brief in length, comprising three pages of a letter submission. They largely challenge the HHRA on points that were addressed fairly and at length in the HHRA. In that sense, the commenters have either misunderstood or mischaracterized the material in the HHRA and the HHRA's interpretation of the data for overall risk characterization of lead and non-lead contaminants.

p. 1, 2nd par. The C of C mischaracterizes the nature and implications of national vs. local Pb-B distributions as a function of socioeconomic and demographic strata. Secondly, the nature and interpretation of Pb exposure data gathering by the Panhandle Health Department is distinct from the overall and broader nature and needs of the HHRA. Site-specific conditions were in fact used to a fare-thee-well in the HHRA.

pp. 2 and 3, Bullets and sub-bullets

Bullet 1 is a general comment about there having been progress. There appears to be no comment on the HHRA as such. No response is necessary.

Bullet 2 misstates the relationship of the HHRA to current and future risk scenarios. How exactly is anything "hidden" in terms of gains? One cannot color the interpretation of the level of current risk by declaring, well, things were worse years ago so let's let it go at that. I don't see the existence of any guidance or comments useful to the HHRA authors. Secondly, the average Pb-B values are tempered in the use of the IEUBK model by having to be the G.M. value corresponding to a 95%-ile value of 10 µg/dl.

Bullet 3, sub-bullet 1 misstates or misunderstands what the HHRA says about lead risks in the overall Basin. It is clear that the residential scenarios for the principal geographical areas all show significant exceedence of the LOC in Pb-B, 10 µg/dl. Secondly, education is no substitute for the physical remedying of soil and other media lead by abatements. We know this, and the topic is treated in the HHRA. Citations by the commenters of such material as the ATSDR information ignore all the qualifications and caveats about such information stated in the HHRA. Furthermore, the HHRA notes that the main lake cannot be characterized as to a fish consumption risk based on the lateral lake data.

Ibid, sub-bullet 2 does not in any way present evidence that the assumptions for child contact with exposure media April through November are unrealistically over-protective. One can't simply claim such assumptions to be inappropriate.

Bullet 4 is largely meaningless, since it ignores the fact that national data for lead exposure cannot be applied to a small area like the Basin. This was noted in a federal document back in 1988, the ATSDR report to Congress on childhood lead poisoning, and in the caveats discussed in the HHRA. The commenters insist on misrepresenting this basic bit of information. As to the second point, lead paint was heavily covered in the HHRA, more so in a number of statistical respects than soil lead. Everything that could be done to give lead paint a thorough assessment was done in the HHRA.

Bullet 5 is grossly uninformed or misinformed as to lead mechanisms of toxicity, lead dose-response relationships, the underlying purpose of a Pb-B measurement, the best time to do a measurement, and why we do this in terms of dose-response relationships. The commenters here have the same problem as comments on this topic from the SNRC. My responses are the same as those for the SNRC set. Refer to those responses. For example, one cannot average out Pb-B values rather than get a maximum expression during late summer, since maximum toxic harm is related to the maximum Pb-B, the toxic harm is irreversible, and one cannot ignore this toxicological mechanistic reality for some vague and irrelevant statistical purpose.

The last paragraph is essentially what the C of C considers a statement of purpose with reference to pervasive Basin contamination rather than comments on HHRA sections. No response is required.

PB Associates

Memorandum

From: Paul Mushak

CC: Sharon Quiring, Marc Stifelman, Sean Sheldrake, Ian von Lindern

Date: 12/15/00

Re: Part 3. Responses to Mining Industry Comments on the Draft HHRA

Part 3: Responses to Mining Industry Comments on the Draft HHRA

Paul Mushak, Ph.D.

VII. Submissions from Hecla Mining and ASARCO

This is the last set of responses to public and other comments on the draft HHRA, those provided by Hecla Mining and ASARCO and collectively referred to as mining industry comments. The comments being addressed were those provided in hard copy via fax. This consisted of the cover letter of transmittal from the law firm HellerEhrman along with a set of comments comprising 48 pages, inclusive of references.

I provide both general and specific responses to comments provided below. My general comments are pegged to the general comments of the mining companies, and my specific comments are directed to the mining companies' specific comments.

VIIA. General Comments

The general evaluation of the HHRA in the industry comments includes basically two themes in critiques of the draft HHRA for lead. First, the comments aver that the HHRA authors and advisors overestimated community-wide toxicity risks in the Basin. Secondly, the HHRA steers risk management decisions as to clean-up strategies based on risk overestimates that the mining interests would judge Draconian and too demanding of resources, according to these comments.

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Pages 1-13 in the industry comments present what they first summarize on pp. 1-2 as their "Fundamental Concerns." They are grouped as "A. Inappropriate Modeling," "B. Potential for High Bias to Blood Lead Data," "C. Preferability of Community Health Intervention Approach.", and " D. Exaggeration of Arsenic Risks."

p. 2 et seq., A. Inappropriate Modeling. The mining industry comments pose the notion that the modeling of lead exposure and risk in the Basin was simplistic. In doing so, however, they largely misrepresent what was done in the HHRA in terms of modeling in the form of IEUBK modeling of children's exposures, the nature of the model, and the implications of the model for risk amelioration in the Basin.

p. 2, 1st full par. The comments challenge the limitations of the model in ways that are incorrect or, at best, misleading. For example, the assertion that paint lead is largely excluded is rebutted by the fact that one can accommodate paint lead in either the multi-source dust lead mode or one can use the alternate source mode, where daily lead intake as paint can be employed. The comments appear to seek to create the erroneous impression that the IEUBK model is basically a soil lead model for children's predicted exposures and any site-specific data showing other sources cannot be accommodated. The above is all that need be said on that point if the authors wish to respond.

p. 2, last par. onto p. 3, top The comments here seem to be a set of rambling, contradictory critiques of the inability of both versions of the IEUBK model as used in the Basin to match the blood lead data. This presents the industry view with a contradictory duality, in my opinion. They seem to be first saying that the modeling does not match the measurements, but at the same time are also asserting that the measurements of Pb-B do not best represent the level of lead exposure of Basin children. One has to ask, which is it that's the problem, the modeling or the measurements!? As I noted in my detailed paper in the 1998 Suppl. 6 issue of Environmental Health Perspectives, discordances in prediction vs. measurement can have various causes.

Ref: Mushak P. Uses and limits of empirical data in measuring and modeling human lead exposure. Environ. Health Perspect. (Suppl. 6) 106: 1467-1484 (1998).

The claim that no Basin-specific model was developed does not ring true. All the environmental measures that were available and quantifiable were used as environmental inputs; the bioavailabilities were ascertained as two values, one for the Box and one for default; and these bracket or approach the likely uptake rate. In addition, accommodations in the overall risk characterization scheme were done for lead paint, augmenting the principal model uses.

The comments state that the model does not show the low average Pb-B values. The statements misrepresent the Pb-B data. They are not "low" in terms of what the tabulations in the HHRA show in Ch. 6 in terms of the number of exceedences of the LOC, 10 µg/dl. Their experts need only read what's available. First, the comments seemingly set up a straw misstatement, i.e., blood leads are low in the Basin, and then attempt to demolish use of the model by noting that modeling says the Pb-Bs are not low.

The comments also attempt to set up a straw issue in terms of the intended uses of the model via EPA-OSWER guidance in the Basin or at any other site: open-ended modeling of lead exposures, factoring in changes in demographics, changes in future land use, etc.

It is not clear what the comments mean by the assertion that smelter emissions and their impact on lead intake and uptake may not apply to the rest of the Basin. They offer no evidence, however, to show why or if, in fact, inclusion or exclusion of "smelter emissions" can be done or should be done. Smelter emissions can in fact be mobilized by a variety of mechanisms for fate and transport that would/ could operate in the Basin. This is broadly discernible, first, in the aggregated environmental flow scheme for lead, first presented in the 1986 EPA lead criteria document, Fig. 7-1, p. 7-2, vol. II of this 4-volume document. Secondly, documented major flooding events have also produced documented measurements by the USGS of suspended and mobilized particles that were mobilized downstream. This would have necessarily included particulate from historical smelter emissions that were (1) dispersed first by air to fallout onto soils, (2) brought into surface runoff carrying suspended smelter fallout particles to the Coeur d'Alene River, and (3) subjected to flood events mobilizing sediments comprised in part of original smelter particulate arriving via (1) and (2).

p. 3, 1st bullet, to top of p. 4 I don't see that there is a big discrepancy here in terms of soil ingestion rates. However, it's something that can be responded to by the HHRA authors. I would note that the comments offer no evidence that "camping" entails no "outdoor" exposures and therefore would not entail as much contact with outside soils. This is a bizarre statement and one that, in any event, entails unsubstantiated speculation.

p. 4, 1st Bullet The commenters are incorrect that waste piles are so remote from contact by mobile (or even relatively immobile) children that they should not be figuring in soil level estimates. The comments indicate no awareness of actual conditions up and down the Basin. For example, Hecla's abandoned concentrator at Burke is across the street from residences, so tailing particles with high contaminant content are free to be transported a very short distance and to pile up by the side of the road. Such close impact likely explains why Pb-B values for young children in Burke/Nine Mile are especially high.

Ibid, 2nd bullet The commenters draw attention to the HHRA assumptions and tabulations indicating that areas away from home pose much of the lead exposure problems for the Lower Basin. However, the commenters note in challenge to that HHRA assumption that it is the home-bound infant and toddler who has the higher Pb-B, compared to older children. This should be responded to by the authors, keeping in mind that the commenters are vague and potentially misleading in this claim and ignore some basic activities among exposed populations. For example:

-- The Pb-B measurements for all children at various years were gathered in Summer, exactly the time period when families with both older children and very young children will be frequenting recreational areas with their children. During the recreational scenario operation, families have their infants and toddlers with them; they are not left at the residence.

--Contaminated beaches will typically be a play area with relatively intense contact exposure via mouthing and other pathways for infants and toddlers under parental and other family member observation when the family is at the beach and other recreational areas; this is what families do at beaches with their youngest children.

--Older children can also ultimately produce increased exposures for their younger siblings at other than beach times by the take-home contaminant dust pathway, by playing at recreational areas and bringing particles home on shoes, clothing, bikes, pets, etc.

p. 5, bullet The commenters dismiss the subsistence scenario as never being more than purely hypothetical. In support of their conclusion, the commenters take the position that the Tribal areas are unlikely to ever practice any traditional subsistence in the future whatever the status of contamination, remediation, or amounts of money spent for remediation. This logic ignores some historical points. The HHRA authors described traditional subsistence scenario as a hypothetical scenario, but they also, correctly, did not state that the scenario's behavioral characteristics for tribe members would never translate into any such future practice, even if only ritually, if the contamination and associated risks were removed. It is the current level of pervasive contamination which the HHRA takes as the reason for the traditional subsistence practices being largely hypothetical. Surely, the Coeur d'Alene tribe would take issue with the notion of their traditional lifestyle being gone forever. The reason the traditional subsistence lifestyle was abandoned in the first place was a very prudent recognition that a century or more of upstream mining waste emissions made continuation of such a practice an unacceptable hazard to life and health. The whole thrust and conceptual basis of the Coeur d'Alene tribal lawsuit presumably resides in this simple behavioral cause-effect reality.

Ibid, 1st full par. The basic premise is in error in these comments. The premise is that when we have any discordance between the model and measurement(s), the model is flawed. This shows ignorance about uses of blood lead surveys, their nature, and how and why EPA employs the IEUBK model vs. isolated Pb-B measurements. The commenters are referred to the August 1998 OSWER directive on use of models vs. blood lead measurements, and the role of each for risk interventions. Again, there is a contradictory stance between what's expressed here and elsewhere. That is, the submission questions the Pb-B measurements, then turns around and claims the model is at odds with these measurements that the commenters criticize.

p. 6: B. Potential for High Bias to Blood Lead Data This section is a series of mischaracterizations of sections on Pb-B measurements in the HHRA. I note these below.

Ibid, par. 1 The participation rate was low. However, the ExSum and Ch. 8 in the HHRA note that any impact of this could be in either direction. The commenters here prefer to assume that the impact would be to overestimate risk.

Ibid and p. 7, pars. 2, 3, 4 in Section The comments here misstate the caveats in the HHRA section dealing with this. The commenters seem to believe that any biasing is to the high end, rather than the low end. This is stated despite the fact that the HHRA makes it clear that there are a number of reasons why the Pb-Bs are likely to be lower. Those reasons for biasing to the low end are rather convincing to anyone informed on the environmental epidemiology of lead and the associated behavioral interactive factors operating with the key parameters for such analyses. Curiously, the commenters in the last par. of B acknowledge the existence of major factors driving to the low end in bias but then ignore it.

p. 7 et seq: C. Preferability of Community Health Intervention Approach

p. 8, 1st par. This par. claims that HUD and EPA guidance exists for soil Pb levels 400-5000 ppm that permits methods other than soil Pb abatement to be used. The commenters actually misread the relevant guidance and even to what that guidance applies. The guidance statements at issue actually deal with interim Title IV §403 of TSCA as described in various EPA-OSWER directives. TSCA §403 guidance should be evaluated separately from the OSWER program guidance and the two should not be confused, the former mainly having to do with lead paint programs in largely urban areas. The distinctions, in their major features, are collectively captured in three OSWER directives: (1) #9355.4-12, EPA/540/F-94/043, August 1994; (2) #9200.4-27, EPA/540/F-98/030, August 27, 1998; (3) # 9200.4-29, EPA 540-F-98-061, December 1, 1998.

It is a misreading of the December 1, 1998 OSWER guidance to claim that remediation options above 400 ppm do not have to include soil lead abatement until soil Pb reaches 2000 or 5000 ppm at legally established CERCLA sites (the commenters note both values).

The 12/1/98 guidance from the AA for OPPTS, Lynn R. Goldman, clarifies confusion about soil clean-up levels addressed in Title IV TSCA §403 and both CERCLA and RCRA sites. This OSWER directive also rebuts the inaccurate statements in this comment paragraph. For example:

[p. 1, par. 1 of Directive] *"...questions have been raised about the relationship between the proposed TSCA §403 rule [proposed June 3, 1998] and the Office of Solid Waste and Emergency Responses' Interim Soil Lead Guidance for CERCLA Sites and RCRA Corrective Facilities (OSWER Directive #9200.4-27P, August 27, 1998)."*

[p. 2, par. 1 of Directive] *"EPA has proposed a 2,000 ppm hazard standard for lead in soil at which children's exposures will be associated with a greater certainty of harm...The hazard standard was intended as a "worst first" level that will aid in setting priorities to address the greatest risks promptly. The proposed §403 regulations and the accompanying guidance are to be used by Federal, State, and Tribal lead paint programs, as well as by the industry performing inspections and risk assessments."*

[p. 2, par. 3, "*OSWER's Soil Lead Directive*"] *"The OSWER soil lead directive that provides guidance for the cleanup of lead-contaminated sites under the CERCLA and RCRA laws is unaffected by this proposal. CERCLA and RCRA soil lead clean-ups should follow the approach in the 1998 directive...The TSCA §403 proposed 2,000 ppm hazard level should not be treated as an Applicable or Relevant and Appropriate Requirement (ARAR), "to be considered" or TBC or media cleanup standard (MCS). As recognized in the TSCA §403 rule, lead contamination at levels below 2,000 ppm may pose a serious health risk based upon a site-specific evaluation and may warrant timely response actions. Thus, the 2,000 ppm proposed standard under TSCA §403 should not be used to modify approaches to addressing Brownfields, RCRA sites, National Priority List (NPL) sites, Federal CERCLA removal actions, and CERCLA non-NPL facilities."*

[p. 3, 1st full par.] *"In the absence of site-specific information, EPA believes that levels above 400 ppm may pose a health risk to children through elevated blood lead levels. The 400 ppm screening level identified in the OSWER soil lead guidance is consistent with the "level of concern" identified in the preamble to the proposed TSCA §403 rule."*

p. 8, 2nd par.

It is a misreading of the August 1998 OSWER directive # 9200.4-27, which clarifies interventional methods, to say that all approaches are equally useful or equally permissible for assessment and use. That directive notes (pp. 5,6; Appendix Fact Sheet) the requirement of a tiered approach, ignored in the industry comments:

"IV. Determining Appropriate Response Actions at Lead Sites

"In selecting site management strategies, it is OSWER's preference to seek early risk reduction with a combination of engineering controls (actions which permanently remove or treat contaminants, or create reliable barriers to mitigate the risk of exposure) and non-engineering response actions...

"As a given project progresses, OSWER's goal should be to reduce reliance on education and intervention programs to mitigate risk. The goal should be cleanup strategies that move away from reliance on long-term changes in community behavior to be protective; behavioral changes may be difficult to maintain over time. The actual remedy selected at each site must be determined by application of the NCP remedy selection criteria to site-specific circumstances. However, this approach recognizes the NCP preference for permanent remedies and emphasizes the use of engineering controls for long-term response actions…."

The comments also mix together various programs in use at different sites giving an indiscriminate grab-bag of modalities that have had differing success rates. The Butte approach essentially permitted the PRPs to get a less stringent level of soil lead cleanup in exchange for paint lead reduction steps. In the case of the Basin, for example, the HHRA indicates that only one in five residences have lead painted surfaces deteriorated enough to produce any likely benefit from such intervention, while the remaining 80% still have elevated soil lead levels absent deteriorating lead paint surfaces.

In the Trail program, there is a joint program with the community and the company, with financial support from Cominco, the historical emitter. However, few or no permanent soil lead abatements appear to have been done, so long-term efficacy of the approach remains unknown. Secondly, the impact zone is relatively contained in Trail, versus the huge impact zone of Basin contamination. Thirdly, the socioeconomic heterogeneity is quite low as is population mobility, unlike the Basin's demographic and socioeconomic profiles for those subsets of the population likely to be maximally at risk. That is, maintaining public education and caregiver awareness in the Basin, with people coming in and out, would be difficult. The Bunker Hill "Inside the Box" Pb-B data indicates that children moving into the Box are potentially at higher risk.

Leadville's approach as seen in its ROD and cover declaration is still largely, in the words of the R-8 Administrator, a "pilot project" approach — requiring close oversight and with no clear or recommended relevance to, or a precedent for, any other site — to include five-year reviews and the pilot project to be "evaluated by a group of outside scientists."

In the words of the Region 8 administrator, the Leadville cleanup level was not intended to be one based or driven by health risk numbers. In fact the number chosen was admitted to be above health-based cleanup. For example, in the Leadville OU #9 ROD's declaration of September 2, 1999, Region VIII's Administrator office notes in the Statutory Determinations paragraph of the ROD that "... *Because this decision will result in hazardous substances remaining on-site, ABOVE HEALTH BASED LEVELS [upper case used for emphasis], five-year reviews of this response action will be required."*

Collectively, the Leadville ROD cleanup value was a purely experimental policy-driven exercise, not health risk driven, and therefore hardly an encouraging science-based, objective model for other sites, including the Basin. Here, again, contradictory stances by the commenters. Science alone is seemingly demanded by the commenters for reliable risk assessment in the Basin, while simultaneously touting for application to the Basin the non-scientific, purely experimental policy-driven Leadville OU 9 ROD cleanup level. What's more, it’s a choice of a level that by the Region 8 Administrator's own admission, is not health-driven.

I do not see, in any of the examples, any modality that comports with what the paragraph says they are, or whether the site characteristics of the Basin allow these to be used.

There appear to be contradictory positions here as well. First, there is insistence on solely site-specific information (see earlier response text) and then simultaneously a reaching out indiscriminately to quite different off-site areas, including one in Canada, to decide what's best for the Basin.

p. 9, par. 1 This par. first offers an unsubstantiated premise and then proceeds to lever further arguments with it. The HHRA makes it clear that it is extractive industry contamination that is the dominant contamination source. This is evident from the various statistical and other analyses described in detail in Ch. 6 of the HHRA. Secondly, while the contamination in the Basin may be stable, as the commenters claim, the impacted populations are not. The HHRA makes it clear that any in-migration is predominantly lower-income, less aware families who would be disproportionately at risk at the present time and with future demographic trends, absent any alteration of this contamination in place for "at least the last 75 years."

p. 9, par. 2 onto top, p. 10 This par. states that dust mat lead can originate from either interior or exterior sources. First, no evidence is presented, only speculation, to bolster the commenters' assertion. This speculation also is rebutted by evidence from other studies showing that in fact mats collect particles from shoes when individuals enter their residences. See, for example, the results of the University of Cincinnati portion of the EPA three-city soil lead abatement demonstration project as described in both the UCinn portion of the study and the final, 1996 EPA Integrated Report of the project describing the use of mats in entryways and their use in assessing dust lead mats. Finally, simple logic as well as the study results dictate that mats collect most of their lead loadings and lead concentrations from exterior soils, since people wipe their dirt-laden shoes on the entry mat. It would be somewhat difficult to argue that people also typically wipe their feet on entry mats when exiting their residence.

Ref: U.S. EPA. Urban soil lead abatement demonstration project: EPA integrated report.EPA 600/P-93/001aF. Research Triangle Park, NC:Environmental Protection Agency, 1996.

The commenters state that direct blood lead to soil lead relationships are low. They then go on to note that the HHRA did not fully assess the allegedly significant role of paint. The commenters seem to be unaware of the fact that soil lead imparts effects on blood lead through various pathways, direct but mainly indirect, each of which has its own contribution to blood lead. The pathways therefore have to be evaluated for what would be the TOTAL contribution. In addition, one can also assess other lead sources contributing to dust pathways. Typical of a number of other studies, the relative size of the direct associations are tempered by the need to do structural equation modeling (SEM), developed by the UCinn group, and employed by that group to show sizeable indirect contributions of soil lead to blood lead. It is difficult to understand why the commenters would not acknowledge these Cincinnati studies in this section, since they cite the December, 1998 paper of Succop et al. (see references) that summarizes all the Western extractive industry sites studied by the group. These authors, developers of SEM, interestingly note that soil lead is more often a more robust source for dust lead than is lead paint in their exposure models applied to Western sites.

In addition to the Cincinnati group, US EPA has evaluated soil lead-dust lead relationships at Superfund sites using SEM. I refer the commenters to the 1995 EPA statistical analysis report by EPA's Dr. Alan Marcus, done for EPA Region 5 using data from the Taracorp/NL Industries Superfund site in Granite City, Madison County, Illinois. Detailed SEM analyses were employed to tease out very effectively a total robust soil lead input to blood lead, even though a direct association was found to be relatively modest in an earlier statistical analysis by authors of a 1994 assessment of lead exposures in children at this site.

Refs:

Marcus AH. Statistical analysis of data from the Madison County Lead Study and implications for remediation of lead-contaminated soil. Attachment 4: Decision Document/ Explanation of Significant Differences: NL Industries/ Taracorp Site. U.S. Environmental Protection Agency Region V, Chicago, IL, 1995. Available from EPA Region V: Waste Management Division, Chicago IL.

Illinois Department of Public Health. Madison County Lead Exposure Study. Granite City, Illinois. Springfield, IL, 1994.

p. 10, 1st full par. The commenters claim that those children with the high Pb-B levels identified in screening efforts were those also having high soil levels. First, the commenters seem to misunderstand the methodology underlying use of inferential statistics to link Pb-B and environmental media lead levels. It is not valid scientifically to use a small or pre-selected set of children identified via a screening program and health department intervention to draw conclusions about their accompanying soil lead levels, since this entails apples and oranges, statistically speaking. One cannot examine soil lead levels vs. Pb-B in children without using the full epidemiological cohorts across the four years of study, i.e., use of all the blood-soil lead pairs to do a full spectrum analysis. This is basic in lead epidemiology. The high blood lead children were identified in a different context statistically and for a different purpose.

Ibid, 2nd full par. The commenters seem to be claiming that the reason there's a health problem in the Basin is because there is low socioeconomic status. That observation, true or not, merely identifies a risk factor for lead exposure, it is not a surrogate explanation for why lead contamination causes both lead exposure and lead toxicity. When one has both amplifying factors for lead exposure and for lead toxicity, it is more necessary to be stringent about lead control, not less. The logic here appears to be a variation of blame-the-exposed-victim.

p. 11, 1st par. The commenters incorrectly and misleadingly claim that it is only the model that invokes a role for dust and soil lead in blood lead elevations. The commenters assert that an expert witness for the government in the litigation phase of this site's actions agreed that children's blood lead levels are not associated with soil lead in the Basin.

Several responses are merited here. First, all the public comments were made to the administrative record for the RI/FS in terms of public comments on an HHRA. The HHRA is not a litigation/court document per se being fought over by expert witnesses. Therefore, the commenters' reference to Dr. Landrigan's deposition and whether he said or did not say something regarding soil lead and blood lead is not directly relevant to the issues at hand for objective review of this HHRA, nor is it appropriate that responses to this comment be focused on Dr. Landrigan's testimony in the separate matter of litigation in the Basin. I am quite familiar with Dr. Landrigan's clinical expertise in pediatric lead poisoning. It's not clear what is Dr. Landrigan's actual published expertise in the areas of exposure pathway analysis, multi-regression analyses using structural equation modeling, valid use of discrete sampling vs. single composites in some geostatistical design framework, etc. or for that matter, the actual context in which his deposition testimony said something or did not say something.

The soil lead-blood lead direct relationship as assessed in the 1999 report of the 1996 Idaho/ATSDR study is tempered by some simple technical problems. First, soil lead operates through several pathway mechanisms to have an impact on Pb-B. This is obvious from the EPA Integrated Report document cited above. I refer the commenters to my response showing that entry mats, with loadings and lead levels linked to Pb-B values, would mainly reflect soil and exterior dusts for obvious reasons. The best statistical analysis to tease out what was going on in this 1996 study in terms of soil lead getting to blood via all well-accepted pathways was not employed. Secondly, the study entailed inappropriate use of basically single or dual sampling per residential unit without prior detailed sampling to establish the presence of heterogeneity in the soil lead levels and their distribution in the Basin yards. Without any knowledge of the nature of the lead distributions in these residential yards, or their heterogeneity, one had to first use multiple discrete samplings to assess whether single or double samples per yard were even adequate.

I refer the commenters to what EPA's RAGS 1989 document says in a number of places about the need to ascertain hotspots and the inherent limitations of single sampling of an exposure unit. These responses also appear in my responses to Dr. Coomes. EPA's 1989 RAGS document treats hot spots in a prescribed way. Hot spot discussions are contained in RAGS at pp. 4-10 to 4-12, 4-17, 4-19, 5-27, 6-24 and 6-28. On p. 6-28, last par., left column:

"In some cases, contamination may be unevenly distributed across a site, resulting in hot spots (areas of high contamination relative to other areas of the site). If a hot spot is located near an area which, because of site or population characteristics, is visited or used more frequently, exposure to the hot spot should be assessed separately."

Absent any prior documentation as to the nature of lead contamination heterogeneity and lead distribution within the yards in the Basin, it would be inappropriate to take one or two samples of yard soil for testing and then say this is a reflection of lead distribution.

In the May, 1999 draft final report of the Idaho/ATSDR study, the investigators found in their statistical analyses additional results that provide good evidence that the soil lead-blood lead relationship would be stronger than indicated in a simple direct analysis.

On p. 38 of the 5/99 Idaho/ATSDR draft final, the summary bullet notes:

" • Children less than ten years of age who played outdoors most frequently on dirt or sand surfaces (including sandbox) had significantly higher log blood lead values than did children who played outdoors most frequently on grass or other surfaces. The proportion of children with elevated blood lead levels differed significantly by outdoor playing surface. Thirty-eight percent (37.5%) of children who played outdoors most frequently on dirt or sand surfaces had elevated blood lead levels, compared with 4.8% of children who played outdoors most frequently on grass or other surfaces."

The above refutes the notion, as do my other responses, that there was no relationship between lead in soil and lead in young children's blood. The more available the outside bare soil was to children, i.e., the soil/sand surface, the higher the blood lead. The less the contact with bare soil/sand, the lower the Pb-B.

p. 11: D. Exaggeration of Arsenic (As) Risks

1st par. et seq., pp. 11-13 The commenters claim that the RfD for ingested arsenic, involving non-cancer effects, is applicable only for a lifetime of exposure, and is therefore inappropriate for the child age band. This can be rejected on a number of grounds, given recent studies. First, we cannot say that the RfD as derived would be inappropriate, since it was developed for cardiovascular and dermatopathological lesions before new data emerged showing that children are at higher risk than adults for As non-cancer effects and that As is handled metabolically by the child differently than by the adult. The use of an RfD for less than lifetime risk is quite appropriate for an age band narrower than lifetime when there is increased risk within that band. That's what we have with children.

The commenters are referred to the NAS/NRC 1999 authoritative document on drinking water As for discussion of children as being at special risk. Discussions include one on p. 232 of the NAS report. Studies show that children don't biomethylated As as well as adults, although the precise role of biomethylation is not clear given current research. Two papers in particular were reviewed and their results basically accepted by the NAS report authors, those of Concha et al., 1998 and Kurttio et al., 1998. They collectively show that impaired biomethylation continues across a broad childhood band. That is to say, the risk band is broader than just infants and toddlers.

The use of the RfD for exposures that occur well into adulthood and certainly for the childbearing years in women, for the specific purpose of protecting against developmental toxicity of the fetus, is called for as well. A very recent paper by Hopenhayn-Rich et al., studying pregnancies and early infant outcomes in Chilean mother-infant pairs, showed that increases in maternal As exposures are related to increases in infant mortality rates in these women.

Ref: Hopenhayn-Rich C, Browning SR, Hertz-Picciotto I, Ferreccio C, Peralta C, Gibb H. Chronic arsenic exposure and risk of infant mortality in two areas of Chile. Environ. Health Perspect. 108: 667-673 (2000).

The commenters claim that the low dose As relationship to cancer is sub-linear. That claim is clearly contradicted by the conclusions of the NAS 1999 report on As, which the commenters cite in their reference list. The NRC report authors note that the available models for low-dose extrapolation do not permit ruling out linear extrapolation. Quoting from its Executive Summary, p. 7, Risk Characterization, par. 3:

"Information on the mode of action of arsenic and other available data that can help to determine the shape of the dose-response curve in the range of extrapolation are inconclusive and do not meet EPA's stated criteria for departure from the default assumption of linearity. Of the several modes of action that are considered most plausible, a sublinear dose-response curve in the low-dose range is predicted, although linearity cannot be ruled out."

The NRC report made it clear that it considered the nature of the low-dose relationship to be driven by the mechanism of carcinogenic action of As. Since the NRC report appeared, additional data have appeared showing that a linear model at low dose would in fact be reasonable. Mass and coworkers, in work described in an SOT abstract, show that direct interaction of arsenic as the trivalent monomethyl metabolite with DNA was seen in tandem with various measures of DNA damage. Damage included: unwinding (nicking) of DNA and production of double-stranded breaks, and/or induction of alkaline labile sites at levels well below inorganic As levels. A number of other measures of damage were positive. These results show methyl-As (III) being genotoxic via DNA interaction.

Ref: Mass MJ, Tennant A, Roop B, Kundu B, Brock K, Kligerman A, DeMarini D, Wang C, Cullen W, Thomas D, Styblo M. Methylated arsenic (III) species react directly with DNA and are potential proximate or ultimate genotoxic forms of arsenic. The Toxicologist (2001, in press): Proc. Soc Toxicol 40th Annual Meeting, San Francisco, CA, March 25-29, 2001.

Ibid, 2nd par. onto top of p. 12 The commenters take issue with the soil ingestion rate for the recreational scenario, duplicating the criticism earlier for lead. Again, they offer no evidence for quantifying an alternative ingestion rate, only unsubstantiated speculation.

VIIB. Specific Responses to the Mining Industry's Specific Comments on the HHRA

A, Data Collection, p. 14 The commenters are superficially correct in noting that the mat at the entry way may not be fully integrating all dust that may arise and distribute internally. However, the fact remains that the mat loading and concentration were found to be particularly useful as a robust marker for interior dust reservoirs actually affecting Pb-B in earlier studies by the Cincinnati group. EPA, using the SEM approach of multiple regression analysis, in its Integrated report (referenced earlier) noted on p. 1-14, 15, Sec. 1.2.3, Cincinnati Study, that:

"...this integrated report concludes, through a detailed structural equation analysis, that there is a strong relationship between entry dust and interior dust in this subset of the Cincinnati study, where the impact of lead-based paint was minimized."

Not all of the residences tested in the Basin in 1996 had lead paint that was deteriorating. The actual value was about 20%. That is, 80% had a minimal input from deteriorating paint lead surfaces.

p. 15: Waste pile sample collection The commenters claim that the absence of fines on waste pile surfaces reduces the actual exposure impact of children playing thereon. This is simply misleading in its main thrust for risk characterizations away from home. I have addressed this issue in responses to other commenters, and commenters are referred to these statement. In summary, waste piles engage children, especially older children, in ways other than simple hand-surface contact where presence of fines would be an issue. The latter applies only to infants and toddlers, not likely to play on piles away from home. Older, mobile children climb waste piles, burrow in and around waste piles, ride bikes over the piles, etc., activities resulting in breaking through and exposing lower depths of piles. This justifies use of deeper depths and mitigates the need for surface fines. In other case, there are plenty of fines. As noted earlier, furthermore, absence of fines is not necessarily widespread. The waste piles around the defunct Burke concentrator have mobile tailings that are very close, across the street, from residences.

pp. 15-17: B. Data Interpretation

Geographic sub-area selection Again, as noted before, there is confusion as to integrating geographic sub-areas and the original five CSM units. The authors need to clarify this.

Background...in surface...and groundwater This may or may not be a valid concern by the commenters. It depends on the relative fraction of total metal in the samples that is dissolved. Relevant data for background levels showing the proportion of total metals that dissolved metals comprise would be helpful.

Screening arsenic concentrations in surface water We certainly know the forms of As in seafood are mainly present as arsenobetaine and/or arsenocholine and the authors should check the species-specific biotransformation processes in freshwater fish as well. However, there may be some confusion here on the part of the commenters. But given that fact, it's not obvious or clear that occurrence of biotransformation processes and transformed metabolites of As in biota preclude assessment via measurement of an empirical, quantitative relationship worked backwards from biota to limnological levels of original As. This relationship of a BCF to water levels is often followed, for example with methylmercury despite there being conversion from inorganic Hg to MeHg in lower trophic organisms, by biomagnification as one works up the trophic ladder. If some level of As, in whatever form, is mathematically linked to an original level of inorganic As in an aquatic system, why does the form of the biotic As preclude the computation?? The only possible way the matter might get muddled is if one cannot measure all forms as to core As content equally well. That could be a problem in a different context, such as if speciation itself for purposes of toxic potency were the focus. In the latter case, see the discussions in Mushak and Crocetti, cited below:

Ref: Mushak P, Crocetti AF. Risk and revisionism in arsenic cancer risk assessment. Environ. Health Perspect. 105: 103: 684-689 (1995).

Yard soil collection results This is a valid concern, and I found the section dealing with validity of combining data sets a bit confusing for yard soils. However, the HHRA does note that statistical tests of compatibility for sample sets collected different ways were done and merging was permissible except for the one case. There was also a reference to an Appendix. The authors might wish to clarify this portion some more. However, I reject the notion that there is such a huge biasing between 175 microns and 250 microns, the ceiling for IEUBK model testing, that one can't use 175 micron fractions. This is nonsense if one reads the scientific evidence. There may, in fact, be a very small fraction of the total sized between 175 and 250 microns in the total particles in a bulk sample. There appears to be some sense in the comment that particles somehow follow a homogeneous particle size distribution, such that one can simply interpolate the missing fraction between 175 and 250. With anthropogenic particles, there is typically a huge fraction below 100 microns, and especially below 10-50 microns. There may also be little between 250 and 175, at least not enough to question the results. This can be discerned in various studies. See, e.g., the plotted histogram data of Duggan et al. for general play areas for children:

Ref: Duggan MJ, Inskip MJ, Rundle SA, and Moorcroft JS. Lead in playground dust and on the hands of school children. Sci. Total Environ. 43: 65-79 (1985).

The case for geochemical waste materials from extractive industry sites is also especially informative. It permits us to say that little in the way of relative lead mass or total particle size fractions lies between 175 and 250. For example, EPA Region 8 reports particle size distributions for all of its study reports involving all those Superfund sites being tested in the young pig bioavailability testing protocol for lead. The protocol included sieving at 250. One can readily see that for the sub-250 particles, which of course would let through 175 particles as well, essentially 100% of the particles are below 175, with no evidence of particles of any substantive amount being 175 to 250 microns.

In the case of the Region 8 report for the Smuggler Mountain NPL site, Aspen, CO, Table 2.2 shows that 100% of the particles below 250 microns are at 125 microns or below. The highest particle size measured was 125 microns, for cerussite.

The Region 8 study of the Jasper County, MO Superfund site is especially telling, since the characterization of the media being studied for bioavailability included data not only on yards and the smelter site, but also mill tailings. The yard and mill tailings size distribution data have relevance to the media types in the Basin. In Table 2.2 of that report, we see that for the mill samples the fractions of particles between 175 and 250 were quite low, with the vast majority of the particles having a maximum size of 110 microns. For yard sample particles, the maximum particle size encountered was 100 microns.

Refs:

Casteel SW, Weis CP, Henningsen GM, Hoffman E, Brattin WJ, Hammon TL. Bioavailability of lead in soil samples from the Smuggler Mountain NPL Site Aspen, Colorado. (Region VIII). May, 1996. USEPA Region VIII Document File, Document Control No. 04800-030-0160.

Casteel SW, Weis CP, Henningsen GM, Hoffman E, Brattin WJ, Hammon TL. Bioavailability of lead in soil samples from the Jasper County, Missouri Superfund Site (Region VII). May, 1996. USEPA Region VIII Document File, Document Control No. 04800-030-0161.

pp. 17-22: C. Exposure Assessment Parameters

p. 17, Assessment of surface water exposures The commenters present a battery of purely speculative statements as to how the parameters selected for the HHRA in exposure assessment would militate against the HHRA choices. One can't rebut plausible assumptions by the HHRA with alternatives that offer little plausibility or credibility.

p. 17 onto p. 18, Waste pile exposures I have addressed this issue in my earlier comments.

p. 18, Exposure frequency this question arose in submissions of early commenters. The authors should clarify and reconcile with the climate record and behavior of the receptors at various times of the year.

Ibid, the recreational scenario soil ingestion rate This seems like a concern that can be responded to readily by the authors.

Dermal exposure pathway I would agree that the dermal pathway for some of the metals may not rival ingestion as to relative impact on risk. However, all pathways contribute to integrated intakes and integrated risks. We are not stratifying risks as simply "higher than" or "lower than."

I do take exception to what the Ruston, WA child data say about intakes based on biomonitoring of urine As. First, the sample size was relatively small especially when stratified as to distance from the site. Second, we don't know how As is handled in the bodies of children vs. adults, in terms of half-lives. Furthermore, we would expect that with a relative half-life for As in the human body being less than that for lead, i.e., several days, then a single-shot As screening could show a large effect on biomarkers for As where any alteration in that child's exposure interactions from parental intervention, etc., occurred. The vulnerability of a urine As to the artifact of parental awareness and control of children's activities is biologically and biokinetically higher than even for lead. Ruston, WA is a community that has been aware of, and concerned about, the ASARCO Tacoma smelter's impacts on the community for many years.

p. 20, to top p. 21, Homegrown vegetable...pathway The statements here misstate and selectively cite the available evidence. First, it is not the case that uptake of lead and arsenic by crops is low. Whether the uptake is low or not depends on a number of soil and phytochemical characteristics, and in any event will depend on soil metal concentrations as well as any uptake factors.

Hattemer-Frey et al., for example, described studies with a cluster of metals typically found at Superfund sites. The uptake rates varied enormously with various soil chemical characteristics and other factors. One cannot simply use, for example, static factors such as that developed by the USDA (Beyes, 1984) for all situations.

Ref: Hattemer-Frey HA, Krieger GR, Lau V. An evaluation of the effect of some soil properties on root uptake of four metals. In: (KB Hoddinott, ed.) Superfund Risk Assessment in Soil Contamination Studies (v. II), No. ASTME STP 1264. Philadelphia, PA: American Society for Testing and Materials.

Some studies of the role of garden vegetables at Superfund or related sites show limited risk, others show considerable risk. It depends on the thoroughness and effectiveness of the study design. A number of studies which simply tested available gardens ad-hoc had limited useful data, and this is not surprising from a statistical outcome standpoint. Such studies are limited by the availability of opportunity to study existing gardens.

Few investigators have systematically studied real-world garden plots in terms of valid statistical design and study execution. Where that was done, it is clear from the results that contaminated soils pose such a health risk that remediation and other intervention modalities typically urge residents not to plant gardens. In some cases, residential soil levels of contaminants are so high, nothing will grow. This is hardly reassuring from the standpoint of net human exposures via other pathways, however. The most thoroughly studied Superfund site in terms of systematic garden plot studies under multi-season, real world conditions by expert teams in this area were the studies carried out at Palmerton, PA, a community heavily impacted with multi-element contamination from two zinc smelters and associated facilities. The results, collectively, led to strong recommendations not to plant gardens or consume any garden crops whatsoever. The details of all these studies are in the EPA Region III Administrative Record for the Palmerton site, in Philadelphia.

The question of the chemical form of As in foods other than seafood has been an area of some contention. The debate over vegetables began with the detailed critique of the topic by Mushak and Crocetti in the arsenic paper cited in its entirety earlier.

p. 21, Use of house dust data The concern about non-lead soil vs. dust relationships is partly correct. The sources of lead in house dust are largely outside soil. The question of missing dust vs. soil relationships for non-lead should be addressed by the HHRA authors.

Ibid, Combination of exposure parameters Again, as was done repeatedly in this submittal and other commenter submissions I reviewed earlier, the commenters attempt to substitute reasonably protective scenario exposure parameters with alternatives that are only rooted in ungrounded speculations.

p.22: D. Exposure Scenarios

p. 22, Subsistence scenarios This compound comment consists of a number of bullets that indicate the commenters are unfamiliar with a number of studies in various publications. The commenters offer the purely arbitrary bit of speculation that the traditional subsistence scenario will never be achieved. I have responded to this in detail earlier and one can refer to these responses.

All the bullets are off the mark, since they indicate unawareness of the key study by Harris and Harper in Risk Analysis several years ago, supporting the figure of 300 mg/d for soil, 300 mg for sediment, etc. The commenters need to consult that paper, since they have not cited it. The paper is:

Ref: Harris SG, Harper BL. A Native American exposure scenario. Risk Analysis 17: 789-795 (1998).

It's also clear that the commenters are not aware that the 1997 update of the Native American tribal factors portions of the EPA Exposure Factors Handbook (EFH) supports the assumptions of exposure factors that amplify those factors based on a typical Eurocentric suburban or rural scenario. This set of comments is, in my opinion, woefully uninformed.

EPA EFH Ref: U.S. EPA. 1997. Exposure Factors Handbook. Volumes I-III. [An Update to Exposure Factors Handbook: EPA/600/8-89/043, 3/89]. Report No. EPA/600/R-97/006, 12/96: Washington, DC: Office of Solid Waste and Emergency Response.

p. 24, Combinations of exposure scenarios Again, the commenters substitute ungrounded speculations as to what they call the problem of overcounting since incremental exposures in their view are somehow concurrent with the baseline scenario. However, they fail or appear to fail to grasp that there are different subsets of receptors who are variably impacted by the residential baseline and the incremental scenarios. We don't double count children when we examine frequency of access to waste piles for older children along with infants and toddlers having exposures obviously restricted to the home, i.e., restricted mobility versus older children.

Besides the matter of double-counting, the commenters don't offer any useful documented alternatives to those factors selected for use in risk analysis in the HHRA. The comments here and elsewhere are riddled with subjective criticisms trying to have the reader draw an inference of implausibility without evidence.

p. 25: E. Characterization of Lead Health Risks This section starts with five paragraphs on lead toxicity characterization.

p. 25, 1st par. The commenters have a reasonable concern here in that the vast amount of accepted scientific evidence for dose-response relationships for lead are largely absent here. I had and still have problems here as well, since the information is there in huge abundance. I would suggest the authors paraphrase any of a number of dose-response tables and text from such authoritative sources as the 1993 NAS report on lead exposure, the 1997 and 1991 CDC Statements on lead poisoning in children, etc.

Ibid, 2nd par. over to p. 26 The commenters misrepresent the strength of low-level lead effects as an accepted body of science in the clinical and public health mainstream. The Stu Pocock paper is not accepted by regulatory agencies or among informed lead scientists and health professionals as showing trivial low-level effects (see, e.g., the 1993 NAS document). The commenters tend to represent a minority view in this, if not an actual fringe view. The commenters should consult: the 1993 NAS report on lead, the 1997 and 1991 CDC statements, the February, 1991 statement on elimination of childhood lead poisoning, the huge section in the 1986 EPA lead criteria document, i.e., Chapters 12 and 13 of Volume 4, and the 1995 WHO-IPCS lead criteria document.

p. 26, 1st full par. This par. is merely an added call to state dose-response relationships. Of course, this is useful, as I noted above. It is a bit of a disconnect, however, that the commenters cite the two CDC statements on childhood lead poisoning but don't communicate the clear conclusions in those statements that low-level lead poisoning in children is an important public health problem for health professionals.

p. 26, last par. over to p. 27 There is a terminology in the HHRA being referred to that is lifted from the 1991 CDC Statement. In the summary portion of that document, lead "poisoning" is noted to not occur below 10 µg/dl. The precise quotation is on p. 3, Table 1-1.

"Table 1-1. Interpretation of blood-lead results...

Class	*Blood lead concentration (µg/dL)*	*Comment*
I	*≤ 9*	*A child in Class I is not considered to be lead-poisoned."*

p. 27, 1st full par. Agreed. I suggested earlier that summary dose-response text for young children can be easily added from any of a number of the current, cited documents.

pp. 27-29,Site-specific Blood Lead and Environmental Exposure Analysis

p. 27 to top, p. 28, Role of socioeconomic status The commenters are not clear as to what point they are trying to make with comments on socioeconomic status. It is well known that SES status is a risk factor in the severity of lead poisoning risk, not the occurrence of risk. The occurrence of risk is there because of the lead contamination. The ExSum and Ch. 8 of the HHRA already make it clear with explicit text that SES aggravates poisoning risk. The commenters cannot argue, obviously, that the reason there's lead in the environment of poor people — and therefore poor people have lead poisoning — is because they are poor; i.e., if they were not poor, they would not have lead poisoning. The premise is clearly untenable and illogical on its face.

p. 28, 29: four paragraphs on paint

1st par. The point's largely misleading. Paint will have a role only if it's present and present in a deteriorating condition or otherwise accessible to children. A vast literature for lead paint and lead epidemiology makes this clear. The commenters then state some simple statistical issues that the HHRA has neither rejected nor is not aware of. So, what's its point? Also, the commenters offer without substantiation the point that lead paint will be affecting the mat lead to the same extent as mining-related yard soil lead.

2nd par. The commenters offer comments about how paint lead is handled in the statistical analyses that are at odds with how detailed the paint lead analyses were. Furthermore, the commenters are referred to the Succop et al. paper in the 12/98 Supplement issue of EHP, describing in detail their findings as to how paint lead plays out in statistical models in Western mining sites, of which this group studied about 11 or so. Those studies showed that, in fact, there were a number of sites where lead paint was not as robust a source as yard soil lead largely arising from extractive industry contamination.

The commenters claim that the HHRA analyses would not sort out a case of paint entry from past activities. They then posit a historically undocumented set of scenarios, whereby former lead paint surface activity could have occurred, even if the current surfaces are intact. First, the soil samples taken for lead analyses were statistically gathered not next to the house, where exterior paint would fall, based on many earlier published studies, but apparently nearer a center point in each yard. Secondly, on purely statistical grounds, the amount of soil next to the house and POTENTIALLY containing lead paint particles as a fraction of total soil encountered by feet would be relatively small. Thirdly, the statistical analyses described earlier in my responses for the 1996 State/ ATSDR study show that blood lead is elevated in those bare soil areas that comprise play areas. Few of these areas, obviously, would be at the drip line.

3rd. par. Arsenic is not present in paint at levels rivaling those in geochemical media, if at all. Its use as a pigment was highly unlikely based on the available literature on paint technology, while geochemical As is a strong correlator with geochemical lead and cadmium. Second, the finding that arsenic is lower in house dust than in outside soil is the finding of a very limited, site-specific situation. The commenters cannot, obviously, extrapolate from one finding to a universal statement. There is, again, a contradiction here. Commenters in parts of the submission demand use of only site-specific data and then indiscriminately throw in isolated findings from sites having nothing to do with the Basin.

4th par. I don't understand exactly what the points of the comments are? A general observation about a relationship not pursued in their comments as to a specific statistical purpose is then combined with a different risk factor in the lower Basin and then claimed collectively to explain the real problem. This is something the authors can readily deal with.

pp. 29, 30: two pars on correlations, Pb-B to environmental Pb

1st par. The commenters assert that the wording in the HHRA as to relative strengths of correlations, Pb-B vs. media, is misleading as to impact of yard soils. I will leave that to the authors as to what all went into formulating that statement, e.g., both direct and indirect pathways from soil to blood lead.

2nd par. The commenters are being simply misleading or misinformed when they note that the soil lead/ Pb-B slope factor seen in the Basin is much lower than assumed by the Model. First, this section in the HHRA discusses the DIRECT relationship of soil to blood, and does not take into account the strong role of soil lead adding to dust lead, and then the dust lead from soil lead having a robust relationship to Pb-B. This requires use of structural equation modeling. This point was also introduced and responded to above, in my earlier comments where I cite the 1995 structural equation modeling analysis used at the NL Industries/ Taracorp site as a reanalysis of the earlier report, a report in which the yard soil to blood lead relationship was, like here, modest. When soil lead acting through dust lead in the SEM was tested for, that connection had a very robust statistical relationship.

pp. 30-31, Source identification, 2 pars.

First par. First, the commenters posit a purely hypothetical, not substantiated role for paint lead for all the Basin children's lead exposures, and then note that this Pb-B increment has to be subtracted from what they imply is a sum of both geochemical lead from mining and paint lead. Nothing is offered as hard evidence or as their own analysis, merely speculations.

2nd par. The commenters attempt to link Bunker Hill Box lead exposures to the children's Pb-B data in the Basin. Quite aside from the obvious fact that it is the same lead source at issue throughout the Basin, the comments indicate a misunderstanding of the actual time points for lead biokinetics, mothers to infants. The *in-utero* damage done by lead is apparently permanent and that's not in dispute. But when the babies are born, maternal, prenatal Pb-B values lose linkage rapidly with the infants' Pb-B values. It is largely irrelevant to seemingly claim that lead exposures measured in the Basin over the last four years are actually occurring in the BOX and are somehow imported into the rest of the Basin. That's a stretch, spatially and epidemiologically.

pp. 31 et seq: F. Application of the IEUBK Model

This section covers about six pages of comments about various parameters associated with uses of the IEUBK model for childhood lead exposures in the Basin.

p. 31, 1st par. The commenters assert that uses of the IEUBK model in the Basin by HHRA authors largely use default assumptions rather than site-specific data. The commenters then list their specific problems with the model's use. Responses are to those more specific comments.

p. 32 to top of p. 33, Geometric standard deviation The commenters offer a largely unsubstantiated or theoretical set of reasons why there should be a differentiation between individual GSDs and community GSDs, arguing that a group or community-wide basis for a GSD weaves in more than inter-individual variability. First, there is their question as to the extent to which inter-individual behaviors are already subsuming environmental heterogeneity by virtue of behavior dictating children "sampling" this heterogeneity in the community. Secondly, they argue that the model describes a hypothetical person whose inter-individual variability likewise "samples" the heterogeneity. It's not clear what sort of a straw issue the commenters first set up and then attempt to demolish.

The authors, I am sure, have a number of responses to this and they should offer them.

p. 32, 2nd par. The commenters here draw upon the GSDs found at other sites to make an argument for this site. Superfund sites differ greatly as to empirical calculation of a GSD. The commenters only cite, quite misleadingly, those which are less than the default 1.6. This is not being aboveboard. Other sites have had GSDs greater than the 1.6. For example, the Bornschein report for the Midvale, UT/ Sharon Steel site reported in 1990-91 that the Midvale community around the abandoned mill and large tailing pond had a GSD more like 1.8.

Secondly, the commenters have argued that the Pb-B surveys and screenings have been flawed. Now, however, they wish the reader to draw the inference that the HHRA should consider use of the empirical Pb-B data set to calculate an empirical GSD for the Basin. There is, here again, more than a whiff of contradiction.

p. 33, Bioavailability

1st Par. The first par. of comments mischaracterizes what the HHRA says about the relationship between measured and predicted Pb-B values up and down the Basin. Actually, in some cases the default was a closer predictor than the Box model.

2nd Par. This par. basically offers a collage of speculations as to, first, why different parts of the Basin will have different geochemical media from extractive industry waste streams, and then to argue why there is variability in level of measured vs. predicted concordance in the HHRA findings. This needs no response, unless the commenters can come up with hard evidence showing geochemically distinct media that in fact differ enough to be associated with different bioavailabilities. It is not enough to say that media may be chemically different, it must be shown that these are not distinctions without a biokinetic or toxicological difference.

3rd. par. The commenters make the blanket statement that Western mining sites are linked to media with lower bioavailabilities. This is both misleading and incorrect, as is the Ruby summary referred to. Also, the *in-vitro* testing has yet to be widely accepted, if at all, at this time. Again, to say otherwise is to be either misinformed or uninformed.

Many studies done jointly by EPA Region 8 and various academic research groups, and using the scientifically valid young swine bioavailability testing model, show relatively high bioavailabilities for diverse geochemical wastes from quite a number of sites. In fact, the Region 8 studies are now the most comprehensive set of valid and credible scientific studies of Western site bioavailabilities anywhere.

A number of these Region 8 studies were cited above in a different context. In addition, there are a number of others, including the 1997 Casteel et al. paper in the peer-reviewed literature.

Refs:

Casteel SW, Brown LD, Dunsmore ME, Weis CP, Henningsen GM, Hoffman E, Brattin WJ, Hammon TL. Bioavailability of lead in soil samples from the New Jersey Zinc NPL site, Palmerton, Pennsylvania, 1996. Doc Control No 04800-030-0159. Region VIII, U.S. Environmental Protection Agency, Denver, CO.

Casteel SW, Brown LD, Dunsmore ME, Weis CP, Henningsen GM, Hoffman E, Brattin WJ, Hammon TL. Bioavailability of lead in slag and soil samples from the Murray Smelter Superfund Site, 1996. Doc Control No 04800-030-0163. Region VIII, U.S. Environmental Protection Agency, Denver, CO.

Casteel SW, Cowart RP, Weis CP, Henningsen GM, Hoffman E, Brattin WJ, Guzman RE, Starost MF, Payne JT, Stockham SL, Becker SV, Drexler JW, Turk

JR. Bioavailability of lead to juvenile swine dosed with soil from the Smuggler Mountain NPL Site of Aspen, CO. Fund Appl Toxicol 36: 177-187 (1997).

p. 34, top The commenters misstate the Maddaloni et al. study, its conclusions and its relevance for epidemiology. The Maddaloni et al. paper merely used a Bunker Hill sample to show, via stable isotopic labeling, what is the effect of meal patterns in adults, NOT CHILDREN, on lead uptake for essentially one individual. This study was not statistically designed to serve as a human epidemiological study of lead bioavailability in the Basin under the full range of exposure scenarios at issue in the HHRA. It is also irrelevant to say we don't have uptake data in the Basin, since the Region 8 studies make it clear that the two bioavailabilities (uptakes) used in the HHRA are not only appropriate, but may even underestimate uptake in some cases.

p. 34, Soil/dust relationship The HHRA used the IEUBK model within all of OSWER's guidance for its use and within all the advisories provided by EPA's Technical Review Workgroup for Lead. That is countered by the commenters by their noting that against this framework, there is some analysis data out there showing a statistical association. The commenters also ignore that, in the HHRA, it is stated that paint's role in association with Pb-B is itself attenuated to non-significance when we use community lead levels in the modelings. This suggests that the "paint" measure in these statistical analyses is a surrogate variable for something else going on in lead pathways. Otherwise, why would "paint" be subject to broader soil lead in the community???

p. 34, Dietary lead intake The commenters are creating a straw issue, in arguing that the default diet intakes need to be (moderately) adjusted downward. They then proceeded to try to demolish what's done in the HHRA modeling. This is nonsense. First, a single study by Griffin et al. chose to use an estimate, and this is not an EPA policy. Secondly, and more important, diet defaults are a minor part of the total lead intakes and uptakes, especially with soil and dust lead levels at issue here. One can substantially change a minor input and still not have a major impact on output. This is misleading in the extreme. Here again, we have contradiction. The commenters argue that diet has to be fine-tuned, yet offer a blanket rejection earlier (see my earlier responses) about garden crops having any role in the diet.

p. 35, Maternal blood lead concentrations

1st par. This large paragraph is erroneous, and its use by the commenters is hard to take seriously. That is, it attempts to use national data to characterize what women's Pb-B values should be in the Basin. The HHRA points out why one can't use national data. The commenters either did not read this passage or they are deliberately ignoring it, an objectionable practice. I refer the commenters to that section and the basis of the statements, in the ATSDR report to Congress on childhood lead poisoning. The statements in the ATSDR report were assembled and reviewed by the National Center for Health Statistics, an agency of biostatisticians who were also the principal architects of the NHANES surveys, and are therefore a credible group whose statements are certainly more authoritative than those of the commenters.

p. 35, Combinations of exposure pathways and scenarios

1st par. Comments about over-counting do not appear credible, since they appear to imply that different-aged kids and different receptors in and out of families can have different exposures than younger kids, but exposures that do occur for older kids somehow comprise over-counting exposures for younger kids. These assertions don't seem to be clear or logical. The HHRA does not appear to invoke scenarios, baseline vs. incremental, that have any substantive hazard of over-counting.

2nd par. The comments about inappropriate use of RMEs for any IEUBK use. because the model estimates a CT in Pb-B, etc., appears (as they state the problem) to be a theoretical misreading of the model's uses. One can use any set of environmental media lead for input lead to the model as would be deemed appropriate. What the model basically says is that when you input either a community mean (GM or AM) or whether you use pairs of data for each of the residents, or whether you use a segment of some distribution of environmental lead levels in whatever media, the output is a CT for whatever that input is. If one selects a group of children at the high end of a distribution of soil leads, and then asks the question, what is the distribution of outputs given that input, the model answers the question accordingly.

p. 36, Application of the adult lead model The commenters simply offer a set of comments in general, vague terms without offering anything to respond to.

p. 37, Absorption fraction of lead from soil These comments are incomprehensible, in that they misstate what the IEUBK model's default bioavailabilities are and misinterpret other points as well. First, the soil lead uptake default for the model is 30%, based on 60% relative bioavailability for soil compared to 50% assumed absolute bioavailability for diet and water, i.e., 50% X .6 = 30%. Where does the 12%, i.e., 20% x .6, come from? See my comments earlier about the Maddaloni et al. study.

p. 37, Geometric standard deviation This topic was already introduced and stated in the mining industry comments for children, with little specific for adults. See my responses to the earlier GSD section.

p. 38, Timing of exposure The comments are a set of speculative observations which do not rebut the reasonable assumptions about timing and frequency in the HHRA. They require no response.

p. 38. Characterization of modeling results. Again, the comments for the discordance or concordance of model vs. measured results are largely qualitative, speculative comments that require no response.

p. 39, Other modeling The commenters ask that other models be considered. The Griffin et al. 1999 model is just a modeling group's use of probabilistic technique. EPA has not replaced the point-estimate approach for the IEUBK model, nor does it appear at this early point that PRA offers any superior alternative to what was done in the Basin for model-driven risk characterizations.

pp. 39 et seq. F. Characterization of Non-Lead Health Risks

This section principally deals with various aspects of arsenic contamination, exposure and risk characterization. The responses are organized by the individual topics presented by the commenters, except for those instances where I have already made detailed responses.

p. 40, pars 1,2: Use of chronic RfD for childhood exposures to arsenic I have already responded at length on this topic.

p. 40, bottom to top of p. 41, Observations of arsenic health effects in U.S. populations The gist of this par. is to say that if As were so potent in terms of cancer potency then we should be having a lot of discernible cancers. However, this has been refuted, whatever the surface appeal underlying this comment, by one having to first calculate all the water As and food As distributions and then estimate, using population densities, what the risk rates, or for that matter, prevalences and incidences, should be. Papers by Smith and coworkers at Berkeley include discussions that address this issue a number of times. These workers have been heavily involved in the epidemiology and biostatistics of population studies of As exposure and mortality/morbidity. The earlier citations are included in the paper cited earlier, Mushak and Crocetti, 1995 in EHP. A newer citation of Smith et al. that has discussions relevant to this issue are:

Ref: Smith AH, Goycolea M, Haque R, Biggs ML. Marked increase in bladder and lung cancer mortality in a region of northern Chile due to arsenic in drinking water. Am. J. Epidemiol. 147: 660-669 (1998).

The Lewis data was highly biased against applicability to the general U.S. population. Unlike the Utah study cohort, the U.S. population is largely not Mormon, not as non-smoking, not as non-drinking, not as healthy, in terms of SES and associated health risk factors, potentially all risk factors that affect the expression of adverse effects of contaminants. However, the commenters appear to ignore that what the Lewis et al. data show is that As levels in these Utah communities are associated with cardiovascular risks.

p. 41, Risks associated with low dose levels The NRC 1999 report, like NRC reports in general, is more authoritative on matters of arsenic cancer models than an isolated EPA meeting four years earlier. That NRC report stated explicitly one could not reject linear low-dose extrapolations for cancer risks from low As intakes. The commenters strangely attempt to elevate the lesser of two sources of authority and to attenuate the more authoritative view. Science is at odds with this strategy. See my earlier responses on this topic.

p. 41, Risk calculations The calculations are straightforward, unlike the impression the commenters wish to convey.

p. 42, Risk characterization results One cannot say, at this point, whether individual effects from COPC metals will be additive or not. Additivity or its rejection requires knowledge of the mechanisms of toxic action for these Basin contaminants. Knowledge to reject inter-organ or inter-tissue toxic interactions is not known by science or the commenters. At this point, additivity is not far-fetched.

The issue of using as child risk reference for As an RfD intended for lifetime exposures was addressed in my earlier comments.

Last par. The issue of tribal subsistence exposure factors and their use for the HHRA were discussed in my earlier responses.

SECTION 4.0
COMMENTS FROM THE TECHNICAL REVIEW WORKGROUP FOR LEAD

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

Transmittal Memorandum
Technical Review Workgroup for Lead (Pb)

An interoffice workgroup convened by
Office of Solid Waste and Emergency Response

Date: October 19, 2000

Subject: Review of Human Health Risk Assessment for the Coeur d' Alene Basin

From: Mark Maddaloni
Kevin Koporec
Co-Chairpersons of the Technical Review Workgroup

To: Sean Seldrake, EPA Region 10

The TRW greatly appreciates the opportunity to review the *Human Health Risk Assessment for the Coeur d'Alene Basin*. Please find attached a compilation of the TRW's comments. Please note that the attached report has not undergone a full review by the TRW. The report was prepared by a sub-committee of the TRW and, after discussion of the review in a TRW teleconference, and in consideration of the urgency of delivering the report to Region 10, it was decided that the report would be forwarded directly to Region 10 without full TRW review.

Please do not hesitate to contact either Mark Maddaloni or Kevin Koporec if there is any way that the TRW can be of further assistance to Region 10.

Respectfully,

Mark Maddaloni, co-Chair, Region 2

Kevin Koporec, co-Chair, Region 4

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

TECHNICAL REVIEW WORKGROUP FOR LEAD

Technical Memorandum

Review of Human Health Risk Assessment for the Coeur d'Alene Basin

Prepared for

Sean Sheldrake
Marc Stifelman
U.S. EPA Region 10
Seattle WA

October, 2000

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U.S. Environmental Protection Agency

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1.0 INTRODUCTION

1.1 Charge to the TRW

This report summarizes comments of the EPA Technical Review Workgroup for Lead (TRW) on the *Human Health Risk Assessment for the Coeur d'Alene Basin Extending from Harrison to Mullan on the Coeur d'Alene River and Tributaries Remedial Investigation Feasibility Study* (July 2000, Public Review Draft) (referred to in this report as the CDAB HHRA, or the HHRA). EPA Region 10 requested this review *to ensure that the HHRA is technically sound and consistent with EPA policies* (August 1 memorandum from Region 10 to TRW). The Region requested that the TRW give attention to the following priorities related to the assessment of lead risks:

- Is the Risk Characterization transparent, clear, consistent, and reasonable?
- Does the Uncertainty Discussion provide context for the risk results?
- Do the predicted house dust concentrations associated with various yard soil action levels support subsequent blood lead predictions and Preliminary Remediation Goals derivations?
- Does discussion of blood sampling methods, participation rates, and age distribution (which changed over time) help to interpret the blood lead screening results?
- Is the discussion of the results from the two modeling approaches sufficient to support risk management decisions protective for human health risks from lead?

The CDAB HHRA included an extensive assessment of exposures and risk associated with chemicals other than lead. These portions of the HHRA were not the subject of the TRW review.

1.2 Documentation and Data Reviewed

Documents provided to the TRW for this review included the CDAB HHRA report (July 2000 Public Review Draft) and various supporting memoranda and data tabulations provided by the Region at the request of the TRW, usually in response to requests for clarification of portions of the HHRA or to supplement knowledge of the historical background of the Basin assessment. Within the CDAB HHRA are contained the following types of information which the TRW reviewed:

- summaries of blood lead, soil, and dust lead measurements made during sampling events that occurred in the period 1996 - 1999;
- summaries of the results of correlation and regression analyses of PbB and

environmental exposure levels of lead;

- summaries of results of simulations run with the Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK model), both community and residence batch runs;

- summaries of the results of applications of the EPA Adult Lead Methodology (ALM);

- results of a sensitivity analyses and risk reduction predictions;

- an uncertainty assessment.

Actual data inputs used in IEUBK model runs were not available to the TRW and, therefore, could not be reviewed, and predictions made using alternative inputs could not be compared with those in the HHRA.

2.0 MAJOR COMMENTS

2.1 Relative Merits of Using the IEUBK Model in Community-mode or Batch-mode

Section 6.6.1 of the CDAB HHRA presents child risk estimates that are based on community-mode and batch-mode IEUBK model runs. In the community mode, geometric mean exposure levels for house dust and yard soils for a given Conceptual Site Model Unit (CSMU) were used as input to the model to predict the geometric mean blood lead concentration and P_{10} for the CSMU. In the batch mode, house dust and yard soil lead levels for each residence were used as input and a geometric mean blood lead concentration and P_{10} were predicted for each residence. The corresponding CSMU values were calculated as the arithmetic means of the individual residence values.

The TRW supports the HHRA in not relying on the results of the community-mode runs to estimate community risk at CSUs or to estimate clean up levels. It also recognizes the utility of the uses of the community-mode runs in the HHRA as part of an exploration of the potential impacts of community yard soil and house dust exposure on risk, and in an analysis of the sensitivity of the model to variations in soil and dust lead levels, as a precursor to using the batch-mode runs to estimate soil clean-up levels (see Section 6.7.6, p 6-55 of the HHRA).

However, the TRW strongly agrees with Section 7.4.4 (p 7-39) of the CDAB HHRA which states the major limitations of the community-mode approach:

> *Use of the community mean input approach and subsequent estimation of community blood lead level means and blood lead level distributions is the least computationally and conceptually desirable of the various approaches that can be employed. The community approach subsumes too much uncertainty simply because it attenuates heterogeneity of lead exposures, and understates the most revealing depictions of blood lead distributions. For this reason, the IEUBK model's user manual (USEPA 1994a, b) discourages use of the model at this insensitive, gross level.*

EPA guidance stresses that, for the purpose of supporting remedial decisions for residential contamination, risk assessment approaches should focus on children who receive their principal lead exposures in the immediate vicinity of their homes (U.S. EPA, 1994). The batch-mode is the preferred approach to this end, because it ensures that risks at each residence are integrated into the site risk estimate.

While EPA guidance focuses on the need to evaluate risks for children at their homes, guidance also recognizes that other exposure scenarios can be important and should be considered where non-residential sources may make an important contribution to lead exposures in a community. In populations where young children spend a large amount of time at locations other than their homes (e.g., neighboring yards, homes of relatives, etc), risk estimates based only on exposure of individual children at their homes may not accurately capture risks associated with each child's actual exposure. At such sites, it may be desirable to include exposures from these community areas in the batch-mode runs. This could be accomplished, for example, by using the multiple source dust model in the batch mode (not in the community mode). Alternatively, activity of the child could be distributed between home yard and community areas having different mean soil lead concentrations, and a time-weighted average used as input in the batch mode. This approach is represented in the HHRA in the application of the IEUBK Box model, although there are other issues associated with this model (see Section 2.2 of this report for further discussion of the Box model).

The community-mode approach was explored in the HHRA as a method for capturing community-wide residential exposures in the risk estimates. However, as suggested in Section 7.4.4 of the HHRA, the results obtained from the community approach should be interpreted with caution, as there may not be any children in the community that are exposed to the actual calculated mean (geometric or arithmetic) soil and dust lead concentrations. Only if a children randomly accesses all yards within the community equally could we expect over time the average exposure concentration for any child to be represented by the community mean exposure level. Random accessing of all yards over a given year (the exposure time step of the IEUBK model) would represent an extreme scenario at many sites, but may reflect the activity patterns of children in the relatively small communities within the CDAB. If this is not the case, then risks at any individual residence may be underestimated or overestimated by community-mode predictions, depending on whether the exposure levels at that residence are lower or higher, respectively, than the community average. The estimates may also be affected by other variables. For example, the relative contributions of home or community exposures may depend on the age of the child in a given home, the presence of older siblings, the geography of the community, or local activity patterns and social customs of the community

2.2 Evaluation of Alternative Approaches to IEUBK Modeling

2.2.1 General Comments

Two approaches were used to estimate lead risks in the CDAB. One approach used the IEUBK model with site-specific exposure inputs and all other parameters kept at default values. In the HHRA and in this report, this model is referred to as the IEUBK default model. A second approach used the IEUBK model with site-specific exposure inputs, an adjusted bioavailability factor (18% total percent available), and a time-weighted soil lead contribution from the residential yard and neighborhood (dust: home yard soil: community yard soil ratio, 40:30:30). These adjustments were based on calibration exercises conducted as part of a Five-year Review of the of the Bunker Hill Superfund Site (BHSS, TerraGraphics, 2000). The adjusted IEUBK model is referred to in the HHRA and in this report as the IEUBK Box model, to distinguish it from the IEUBK default model. The HHRA presents risk estimates, as well as assessments of post-remediation risks assuming various clean-up action levels, based on both the IEUBK default and Box models.

The TRW supports HHRA in not relying exclusively on the IEUBK Box model to estimate pre-remediation risks in the CDAB (i.e., percentage of children exceeding 10 µg/dL, P_{10}). The Box model was calibrated to agree with the downward trend in post-remediation blood lead concentrations observed at the BHSS. Factors that may have affected this downward trend (e.g., decreased soil and dust intakes resulting from intervention and educational efforts) may not be operating or may not be as important in the CDAB. Ideally, if adjustments were to be made to the IEUBK model for its application to the CDAB, such adjustments should be based on the available information about exposures and blood lead concentrations in the CDAB and not at the BHSS. However, the extensive experience at the BHSS could be applied to the CDAB if there were a better understanding of the exposure factors that contributed to the downward trend in the blood lead concentrations at the BHSS, and whether or not these same factors affect blood lead concentrations to the same degree in the CDAB.

Aside from the extensive data base on the presence of lead contamination in the CDBA, the HHRA does not present site-specific data applicable to estimating specific parameters of the IEUBK model (see further discussion below). In the absence of data to estimate specific parameters, consideration of non-default choices can be useful for range-finding and sensitivity investigations. The blood lead concentrations and risk estimates based on the Box model represent an example of this, in that the Box model imposes certain assumptions that are thought to be valid at the BHSS, and the differences between the predictions made with the default and Box models show the impact of these assumptions. For example, if the fractional absorption of lead is lower than the default values, and there is a 50% contribution of community yard soil to soil lead intake in the CDAB, then the predicted blood lead concentrations will be lower than those based on the default model. The results of the Box model runs are interpreted from this perspective in the HHRA (see Section 7.4.4, p. 7-41, HHRA). At this time, there does not appear to be an adequate basis for determining which of the two models provide more accurate risk predictions in the CDAB. However, the differences in the predictions from the two models are not large, given uncertainties associated with both models, and it could be readily argued that actual risks fall within the range of predictions from the two models. Comparisons of the mode predictions with observed blood lead concentrations do not completely resolve this issue because of uncertainties regarding the representativeness of the blood lead data. These uncertainties are discussed at length in the HHRA (Section 7.4.1) and in this report (see Section 2.3 of this report). However, uncertainties not withstanding, the blood lead data do not exclude predictions from either model as being applicable to the CDAB.

It is also important to note that the soil and dust measurements used in the IEUBK model represent the 175 µm fraction, rather than the 250 µm fraction that is more commonly used in CERCLA site assessments. While, as is explained in the HHRA (Section 7.4.2, p. 7-29, HHRA), the smaller particle size fraction may better represent the fraction that adheres to the hands of children, it also is likely to have been enriched with lead, relative to the 250 µm fraction. The TRW has recently provided clarification and further guidance on this issue (U.S. EPA, 2000). Therefore, risk estimates based on the 175 µm fraction would be expected to be higher than those based on the 250 µm fraction from the same samples. This introduces an additional conservative (health protective) bias into the risk estimates. Another way to view this, is that, had the 250 µm fraction been used as the basis for the soil and dust concentration terms, the risk estimates based on the IEUBK model would have been lower by some unknown degree. The use of the 175 µm soil and dust fractions also has relevance to the interpretation of the bioavailability adjustment used in the IEUBK Box model (see below).

2.2.2 Bioavailability Adjustment

The bioavailability value of 18% was applied as an alternative to the model default of 30%. No data specific to the bioavailability of lead in soil and dust at CDAB are discussed in the HHRA and such data apparently have not been generated at the site. The TRW's short sheet, *IEUBK Model Bioavailability Variable* (U.S. EPA, 1999a), discusses methods that can be used to study bioavailability of lead and which have been used in practical applications for other Superfund sites. The TRW recommends that bioavailability studies of soil and dust, or other relevant data, should be used to support a site-specific bioavailability value for the CDAB. However, as a means to provide information regarding the sensitivity of model predictions to this parameter, consideration of alternate bioavailability values, such as that used in the Box model, can provide useful information.

The TRW understands the intent in the HHRA in interpreting the bioavailability adjustment as a surrogate for adjustments in one or more of several variables that relate soil and dust exposure levels to the amount of lead taken up into the blood (see Section 7.4.4., p. 7-41, HHRA). However, the TRW does not endorse use of the bioavailability term in this way. Segregating the various factors that may affect lead uptake would allow one to consider the potential effects of these factors that may influence uptake of lead by children in the CDAB. For example, the CDAB lead concentration data are based on samples screened to a 175 µm sieve size. This may provide relatively conservative estimates of the lead concentration compared to a more common practice of using a 250 µm sieve size. To the degree that concentration estimates tend to be conservative, so would estimates of lead uptake in the model runs (see below). There is also a potential for some decrease in the soil and dust ingestion rates for children in households where health concerns about lead may have caused parents to use increased care in cleaning and supervision of children's activities.

Another uncertainty in extrapolating a bioavailability factor for the CDAB from BHSS data is that it is possible that exposures in the CDAB may be a mix of lead from the smelter and lead from mine wastes, or other sources, which may have different absorption fractions.

The relative contribution of these sources may change with location in the CDAB (e.g., with upwind or downwind from the smelter, or up or down gradient from the smelter), and may change with remediation. For example, at some locations in the CDAB, historic smelter emissions may contribute more to lead in house dust than in yard soils. If lead in smelter dust has a different fractional absorption than lead from other sources, removal of yard soil may change the absorption fraction of the lead to which children would be exposed at that location. There is some support for this possibility in the BHSS, where the calculated bioavailability factor which resulted in better agreement between the IEUBK model predictions and observed blood lead concentrations changed (increased) over time as the remediation proceeded (see Appendix Q, HHRA).

Since the bioavailability adjustment had a pronounced impact on predicted blood lead concentrations and risk estimates, it would be informative to more directly display in the assessment the effects of changes in bioavailability (either directly or as a surrogate modifying lead uptake) on lead risk predictions. This might take the form of graphs and tables that show a range of choices for the parameter value and resulting changes in risk. Given the lack of information specific to bioavailability, such presentations could show the effect of a potential site-specific modification to lead uptake through undetermined mechanisms. An example of this is provided in the attached Figure 1 which shows the impact of various assumptions about lead enrichment in the 175 µm fraction relative to the 250 µm fraction on lead risk. The TRW notes that the IEUBK modeling assumptions regarding bioavailability (or more generally lead uptake) need not be linked exclusively to the multi-source soil exposure scenario presented in the Box model.

2.2.3 Partitioning of Source Contributions to Soil Dust Ingestion

Exposures for children at sites other than their homes were incorporated into the Box model results (using the batch mode calculations) by assigning to each a child a fraction of total soil exposure at home and a fraction of total exposure to an *average* community yard soil concentration (i.e., house dust: yard soil: community soil ratio, 40:30:30). This scenario would have particular relevance for those (often older) children who would spend much of their time away from home playing at a variety of residences, parks, or other areas in the community.

The basis for the 40:30:30 ratio derives from structural equation modeling of the data from the BHSS, which indicated a significant effect of community yard soils on blood lead concentrations (Appendix Q, HHRA). The use of this ratio in modeling lead risks in the CDAB assumes a similar community yard soil contribution in the BHSS and CDAB. The HHRA concludes that this is the case from a stepwise regression analysis of the CDAB data (Section 6.4.2, p. 6-23), This, together with the experience at the BHSS and the expected similarities in the Basin communities, in terms of behavior patterns of children, were the empirical bases for retaining the 40:30:30 ratio in the application of the IEUBK Box model to the CDAB. Although this is a major conceptual change from the default model, the impact of use of the 40:30:30 ratio on risk estimates appears to be relatively minor; the difference between the predicted blood lead concentrations when the default ratio of 55:45 or the 40:30:30 (or a 75:18:7) ratio were assumed in the model was relatively small (Table 4-28, Appendix Q of the HHRA). Thus, from a risk assessment perspective, the modification is of minor consequence.

The concept of including a community contribution to soil lead intake deserves further comment because of its potential utility at other sites. EPA guidance has encouraged the consideration of alternate sources of dust lead intake, other than that occurring at the home. This is the rationale for including the alternate dust source option in the IEUBK model. In the HHRA, the community average of yard soils was used to represent the soil lead concentration of the fraction of the soil lead exposure occurring away from home. There are many sources of dust in a typical community, such as deposition from industrial activity and vehicular traffic, that are not derived from soil. Consequently, an aggregate of individual property soils cannot fully represent community dust exposure. Nevertheless, the use of soil data in the absence of data from these other sources has the effect of assuming that the concentration in the unmeasured sources is the same as the aggregate community soil, not that the unmeasured sources do not exist. The community average serves as a reasonable central estimate in the absence of any information on additional sources of community dust or the behavior patterns of specific children. As an example of the potential utility of this measure, highly mobile children who lived at residences with *clean* soil (e.g., after yard remediation) may still have elevated risks due to access to lead at other yards in the community. The TRW would caution, however, that a community *average* concentration term is a non-specific measure. Risk calculations in which a child's exposure is assumed to be represented by a time-weighted average of home and community average values, may serve to indicate the importance of community wide lead sources for a highly mobile child. However this approach is of limited value in supporting clean-up decisions for specific non-home properties, for example daycare centers, schools, roadsides, and other public areas. A more useful alternative for these types of exposures would be to model results specific to contamination levels at specific schools, daycare locations, local parks (see Section 2.5 of this report for further discussion).

A specific technical concern pertains to how community *average* concentration values were calculated for use in IEUBK modeling (as applied in the Box model and in *community* mode calculations with the default model). As noted above, a rationale for use of a community average concentration term is that an (idealized) highly mobile child would be exposed to contamination throughout a community and the summation of these many events of contacting different concentrations would be equivalent to exposure to a lead concentration equal to the community average values. Under the circumstances where this scenario is applicable, explicitly calculating the summation of exposures will lead to the use of an arithmetic mean and not a geometric mean exposure concentration term. This may be illustrated with an example. Suppose that on three days, a child is exposed at three different locations with lead concentrations of 30, 300, and 3000 ppm. Further, assume that on each day the child ingests 0.1 g of soil at the exposure location. Therefore on the three days, the child has a lead intake from soil of 3 μg, 30 μg, and 300 μg, respectively (30 μg/g x 0.1 g/d x 1 d = 3 μg, etc.) The daily average lead intake for this period is 111 μg/d. For comparison, the arithmetic mean soil concentration at these locations is 1110 ppm and the geometric mean concentration is 300 ppm. Daily intake rates calculated using the arithmetic mean soil concentration value reproduce the daily lead intake level for the child (1110 μg/g x 0.1 g/d = 111 μg/d). However, an intake calculation using the geometric mean understates daily lead intake by more than a factor of three (300 μg/g x 0.1 g/d = 30 μg/d).

2.3 Use of Blood Lead Survey Data

Substantial efforts have been made to collect data on blood lead levels on children and adults living in the CDAB. The HHRA reports that through a combination of efforts in 1996-1999, 524 blood samples representing 424 children under age 9 years of age living in 843 households were collected in the Basin.

The blood lead data in CDAB were collected as a public health service provided to Basin residents and have been utilized by local public health authorities (Idaho Department of Health and Welfare) to provide advice and assistance to children found to have elevated blood lead levels. The HHRA reports that 50 children received follow-up assistance due to the detection of blood lead levels above 10 μg/dL. The majority of children re-screened after public health intervention showed a reduction of blood lead levels from their prior elevated levels indicative of a benefit of this intervention program.

The effort to screen children for elevated blood lead levels in the CDAB comports with CDC recommendations. CDC guidance succinctly describes the value of blood lead screening programs:

> *Blood lead screening is an important element of a comprehensive program to eliminate childhood lead poisoning. The goal of such screening is to identify children who need individual interventions to reduce their BLLs [blood lead levels].*

Blood lead screening may or may not provide data that is representative of the population of concern.

The blood lead screening data in the CDAB also serves the important purpose of demonstrating the presence of continuing risks of lead exposures to the Basin children. Basin wide, 12.5% of tested children up to 7 years of age had blood lead levels above 10 μg/dL (see Table 6-4c, HHRA). In some communities in the Basin, the risks were higher: 22%, Burke/Nine Mile; 19%, Wallace; 14%, Kingston; and 25%, Lower Basin. Risks of elevated blood lead levels were also higher in the younger groups of screened children. Basin wide, 19-26% of tested children one to three years of age had blood lead levels above 10 μg/dL. In some communities, in the Basin the risks were higher in this age group: 50%, 2-3 years, Burke/Nine Mile; 22-40%, 83% 1 years; Wallace; 2-3 years; Kingston; 20-50%, 1-3 years, Lower Basin (the smaller numbers of children make these figures less accurate) (Table 6-5, HHRA). These results serve to demonstrate the need for further attention to reduce sources of lead exposure in the Basin and the need to continue screening and interventions to reduce lead exposures.

However, in interpreting these data it is important to recognize that blood lead screening efforts were not intended to constitute a research investigation of subjects living in the Basin. Individuals were not randomly or systematically chosen for screening as part of a statistical study. Therefore, the screening data must primarily be interpreted as information regarding the children and families who desired screening. It should not be assumed, in advance of careful examination, that the data on screened children is also representative of the majority of children who did not participate in the screening programs. This issue is discussed in some detail below.

Blood lead data collected in the CDAB were used in the HHRA in three ways: 1) to characterize age-related and geographic patterns of excessive blood lead concentrations; 2) blood lead concentrations predicted from the IEUBK model were compared to observed blood lead concentrations in order to assess the effectiveness of various assumptions made in the model for describing current blood lead concentrations; and 3) blood lead data were used in correlation and regression analyses to evaluate relationships between environmental levels and blood lead concentrations in the Basin.

The HHRA takes great care in discussing the limitations of the blood lead data for the above three uses in the risk assessment (see Section 7.4.1, HHRA). The TRW supports the uncertainty assessment of the blood lead data that is presented in the HHRA. In reviewing the documentation for the blood lead data in the HHRA, the TRW arrived at a similar conclusion; that several issues limit interpretations of both the empirical comparisons and the regression analyses. These include: 1) representativeness of the data with respect to the Basin community; 2) sampling bias; and 3) the potential effect of intervention on blood lead concentrations in the community (see detailed discussion below). The TRW concluded that the information presented in the HHRA that relate to these issues suggests that the data do not provide an adequate basis for reliably estimating central tendency blood lead concentrations, percentiles or the percent above 10 µg/dL, or other population parameters. Therefore, the data should be used with great caution and with appropriate consideration of the uncertainties associated with the method of solicitation of participants in the survey, particularly if it is used to characterize blood lead levels in the community. This has particularly important implications for extrapolating any results of these analyses to areas of the CDAB not sampled, or to extrapolations over time, such as post-remediation blood lead concentrations. In view of the limitations of the blood lead data, the TRW supports the approach adopted in the HHRA of basing risk estimates on the results of the IEUBK model runs. This approach is consistent with EPA Office of Solid Waste and Emergency Response (OSWER) guidance (U.S. EPA, 1994). The observed blood lead concentrations support the general outcomes of model runs, that the risk of exceeding a blood lead of 10 µg/dL is greater than 5% is substantial for children who live on many of the properties in the CDAB. A more detailed discussion of the blood lead data are provided below.

2.3.1 Representativeness of the Data

General Issues Concerning Representativeness

The TRW supports the HHRA in its conclusion regarding the blood lead survey data (Section 7.4.1, p. 7-23, HHRA):

> *The nature of this turnout* (i.e. participation in the blood lead surveys) *raises questions about the reliability of using these data in the HHRA and subsequent remedial decisions.*

Blood lead data can provide information on relationships between environmental exposures and blood lead concentrations of individuals in the sample group; however, if such analyses are to be extrapolated to the general population of interest, in this case, residents in the Basin, the blood lead data must represent the entire CDAB population. A sample is likely to be representative if non-biased sampling methods are employed, such as random sampling (equal probability of selection of any individual or home) or stratified random sampling (probability of selection of any individual or home depends upon which strata to which they are assigned. If the sample is not random, it may have a bias which may result in the sample mean not reflecting the CDAB mean (this also applies to other descriptive variables of the sample and corresponding CDAB population parameters). A biased sample may still be used to estimate CDAB parameters, however, to do this, an understanding of the nature and quantitative effect of the bias is needed so that sample estimates can be adjusted to account for bias.

From the outset, the collection of blood lead data in the CDAB was never intended to provide a random sample for an epidemiological study. Blood lead data were collected as part of a public health service provided to CDAB residents. Thus, it would only be fortuitous if the sample turned out to approximate a random sample. Furthermore, data were not collected to specifically evaluate biases in the sample, although some data were collected that may be useful for this purpose.

The lack of a random sampling design in the blood lead program presents challenges for use of the data in the risk assessment, however, it should not preclude all use *a priori*, as the data do provide valuable information on a substantial number of children. In evaluating the data, all factors that might contribute to bias in the estimates need to considered and potential biases need to be identified and quantitatively explored, if possible. An exploration of information available to evaluate and adjust for sample bias is provided in the HHRA (Section 7.4.1, HHRA) and potential approaches are described in Section 2.3.2 of this report.

CDAB Sampling and Sample Size

If the sample is random, it can adequately represent the population even if it contains a relatively small fraction of population. However, concern for the representativeness of the sample increases as the fraction sampled becomes small. One of the concerns about the CDAB sample is that it captured a relatively small fraction of the target population. Child blood lead data used in the HHRA derive from surveys conducted during four consecutive summers, 1996-1999. In 1996, a CDAB-wide survey was conducted which attempted to capture all potentially impacted homes within one mile of the Coeur d'Alene River (essentially the entire flood plain), excluding the BHSS. In 1996, there were approximately 6252 homes in the CDAB. Among these, 2700 homes were identified as potentially subject to lead or other metal exposures and residents at 843 homes agreed to participate in the survey; blood samples were obtained from 98 children (ages 9 m-9 yr), or approximately 9% of the estimated number of children in the CDAB in identified impacted areas (1025-1120, p 6-9 of HHRA). Approximately 200 additional homes were sampled in subsequent sampling years. In 1997, samples from 26 children were collected in the impacted areas, 11 of whom had been sampled in 1996. In 1998, samples from 128 children were collected and 272 children provided samples in 1999. Thus, the total number of samples available for the assessment was 524. Approximately 100 children were sampled twice, therefore, the total number of children represented in the sample was approximately 424. This represents an unknown fraction of the population of children that lived in the CDAB over the four-year sampling period, including children who may have entered (included births) or left the area since 1996. The fraction of the children sampled may have varied across communities in the Basin.

In addition to differences in sample size, there were other notable differences in the four surveys. The HHRA does not provide much information on the sampling approach used in 1997 or 1998, for example, the extent to which it may have been targeted to certain groups of people, or geographically distributed within the Basin. The 1999 survey offered a cash incentive for participation, and was more aggressively promoted within the community (p. 6-9, HHRA).

2.3.2 Sources of Bias and Approaches to Evaluating Bias

Given the sampling objectives and approach, and the relatively small fraction of the population sampled, bias is a concern in extrapolations made from the sample to the CDAB population for the following reasons. Among the sampling data, the 1996 study came closest to being a systematic effort to capture all residences in the CDAB. However, because blood samples were obtained from only 9% of the potentially impacted children CDAB in 1996, there is no assurance that this study was representative of the community.

In the 1997 -1999 screening efforts, community residents were asked to take the initiative to bring their children into clinics for blood sampling. While a higher participation (272 children) was achieved in the 1999, the entirely self-selected nature of the participants reduces confidence that this sample would be representative of the non-sampled members of the community. It should also be noted that the later screening efforts did not limit participation to children from areas likely to be impacted by metals contamination, as was the case in 1996. As a result, that the numerically greater number of participants in1999, relative to1996, may have included a larger fraction of children who lived in areas that had lower potential for contamination.

Other data may be available to help judge the likelihood that data for screened children would be likely to be representative of the community as a whole. Relevant information would include consideration of factors that may be associated with lead risks such as age, residence in more contaminated locations, residence in properties in poor repair, and socioeconomic status. Data to allow a comparison of demographic characteristics of screened children and the community as a whole are unfortunately very limited. Data on factors such as socioeconomic status were not collected for screened children (unless a high blood lead value triggered a home intervention) and, therefore, cannot be compared with the larger community. However, age is one significant risk factor for which there is comparative data, and unfortunately, the younger groups of children that are at highest risk are substantially under represented in the group of screened children. This indicates that, taken as a whole, the screened group may be at somewhat lesser risk of elevated blood lead levels than the community at large. The deficit of young children in the screened group also indicates that the factors that motivated parents to participate in screening were not reflective of lead risks as they would be evaluated by public health professionals.

The HHRA discusses different hypotheses that have been offered concerning the potential biases in the available blood lead data (Section 7.4.1, p. 7-22, HHRA). One set of arguments suggests that parents with a greater level of concern about lead risks elected to have their children participate in screening. Such parents would be likely to act on their health concerns so as to limit their children's exposures to lead (e.g., limiting places of play, more contentious cleaning of dust at home or attention to hand washing and other hygiene measures). The TRW believes that this proposal has plausibility and that it corresponds with concerns of TRW about potential biases in some blood lead investigations conducted at other sites.

Alternately it has been contended that in the 1999 screening event, where the participation rate was greatest, the payment of a 40 dollars compensation to participants would have resulted in a disproportionate participation by lower income families. It is then argued that children in lower income families would have greater risks of elevated blood lead levels. In this regard, the TRW observes that, while socioeconomic variables have been shown to have correlations with lead risks in some other studies, caution needs to be exercised to avoid over interpretation of this issue. First, it is not clear that the payment of compensation to participants was the predominant factor in securing the somewhat larger participation rate in 1999. Considerable additional effort was invested in 1999 to inform and encourage participation in the 1999 survey. Secondly, to the extent that children in lower income families may have increased risks of elevated blood lead, such a correlation would be expected to result from more fundamental underlying factors, not monetary income itself. Some (not all) families experiencing economic hardship may also lack time or resources to provide for as much supervision of children as they would desire. Therefore, it is not clear that parents in families under such stress would have the option of dropping other commitments to take children in for screening. The TRW does not believe that it is appropriate to make the assumption that parents with lower incomes would provide less attention to environmental risks to their children.

Potential sources of bias can be proposed, and then an evaluation made as to whether or not data are adequate for quantitatively assessing the direction and/or strength of the bias. Examples of potential sources of bias include:

- Neighborhood clustering could result in certain areas of the CDAB being under-represented in the sample (spatial bias).

- Parents with younger children might have been less inclined to provide blood samples from their children. This would result in an age bias in the sample.

- The inclination to allow samples may have been influenced by duration of residence which could have affected knowledge and perceptions of the extent or importance of the problem.

- Differences in socioeconomic status (SES) could affect the inclination to allow sampling; for example, lower SES residents may have placed a higher or lower priority to lead as an issue for their families than higher SES residents.

- Information about environmental lead levels or blood lead levels could have influenced participation in the survey. For example, parents who more strongly suspected that there was a lead problem in their community may have been more motivated to participate.

- Cash incentives for participation (discussed above).

The above examples can be translated into a series of specific queries directed at the existing data to determine if available data suggest or do not suggest bias in selection, or an unequal probability of response. Examples of these that could be explored include:

- Were the sample statistics stable over time?

- Were the responders equally distributed geographically in the CDAB and within the CSUs?

- Did the response rate vary across communities?

- Are SES scores similar in the sample and CDAB?

- Are other demographic variables similar in the sample and CDAB (e.g., age, age of housing, residence time)?

Despite a rather large variation in the level of participation in the blood lead monitoring study over the 4-year period (26-272 children per year), minimum, maximums, arithmetic and geometric means and standard deviations of the sample blood lead measurements remained remarkably constant from year to year (see Table 6-1, HHRA). This would suggest that, if there was a strong bias, it may have been relatively constant from year to year. This outcome would also be expected if the samples were indeed representative of a stable population. On the other hand, the percent participation in the blood lead survey varied with age (see HHRA Table 6-4a). This would suggest a possible age bias or under representation of younger children relative to older children.

2.3.3 Potential Effects of Intervention on Blood Lead Concentrations

Another time-related consideration is the impact of community awareness on the time course of blood lead concentrations within the CDAB. Community awareness can and does play a role in affecting short-term behaviors, through temporary decreases in contact with lead sources and consequent transient decreases in blood lead concentrations. Questioning about hygiene and home conditions at a time preceding blood sample collection may promote actions that would tend to reduce risks of elevated blood lead levels. Since there is evidence that individual level contact with parents is important to the success of intervention efforts (Kimbrough, 1994), such studies may implicitly include an important individual level intervention component. This was most likely the case in the CDAB where the blood lead and environmental surveys were specifically intended as part of public health service to the community residents.

In the CDAB, nurses visited homes where blood lead concentrations were considered to be elevated (greater than 10 µg/dL). Blood lead measurements taken in homes after a nurse visited that home may reflect the impact of the nurse-visit, and may not represent the blood lead that would be expected in that exposure scenario, had the nurse-visit not taken place (e.g. a new resident of the home). It is not clear from the HHRA whether blood lead measurements taken after a nurse-visit were excluded from or included in analyses reported in the HHRA. However, the TRW was advised by Region 10 that, if a second blood lead sample was collected as part of or as a follow-up to a nurse-visit, these data were excluded from the analyses. Therefore, nurse-visits are likely to be less of a factor in analyses of blood lead concentrations measured within a given sampling year. However, it is possible that blood samples may have been obtained from children who lived in homes that received a nurse-visit in previous years.

2.4 Use of the EPA Adult Lead Methodology (ALM)

The ALM was used in the HHRA to estimate Preliminary Remediation Goals (PRGs) for adult non-residential exposures, including occupational exposures and recreational exposures at upland parks and other Common Use Areas (CUAs). The EPA ALM includes algorithms that can be used to predict adult blood lead concentrations associated with site soil lead exposures or soil PRGs (U.S. EPA, 1996, 1999b).

PRGs were estimated based on central tendency and reasonable maximum exposure (RME) assumptions about exposure frequency and soil ingestion rate (see Section 6.5.2, pages 6-31 – 6-33, Tables 6-31 – 6-33 of HHRA). All other inputs to the ALM were default values from U.S. EPA (1996). The central tendency exposure frequency for the occupational scenario was 43 day per year which represented a 5 day per week construction project having a 2-month duration. The RME estimate was 195 days per year, representing a 5 day per week, 9-month (39 week) construction season. For CUAs, the corresponding central tendency and RME frequencies were 16 days per year and 32 days per year, respectively. For upland parks, the corresponding central tendency and RME frequencies were 15 days per year and 30 days per year, respectively. Soil ingestion rates for the three scenarios were as follows (central tendency, reasonable maximum): occupational, 0.1, 0.2; CUAs, 0.05, 0.1; upland parks, 0.05, 0.1.

The TRW supports the HHRA in the decision to calculate PRGs for non-residential soils based on the EPA ALM and supports the general approach used in applying the ALM at the site. However, several details in the application of the methodology were inconsistent with guidance developed by the TRW (U.S. EPA, 1996) and may have resulted in increased uncertainty in the risk estimates (Section 6.6.3, p. 6-46, Tables 6-57 – 6-60, HHRA) . These include the following:

- The EPA ALM should not be used to estimate PRGs for exposures that are less the three months in duration or less frequent than one exposure episode per week. Shorter exposure durations and lower exposure frequencies are not sufficient to achieve a quasi-steady state blood lead concentration, which is a required assumption for use of the ALM for predicting either PRGs for blood lead concentrations. The derivation of several of the parameters in the ALM (biokinetic slope factor and the absorption fraction) is based on steady-state observations. Furthermore, the relevance of the health criterion (10 µg/dL) to short-term exposures is less certain than it is for chronic exposures.

- The averaging time used in the EPA ALM should reflect the actual exposure duration. In the HHRA, the averaging time was the number of exposure days per year divided by the number of days in the year, even when the assumption made in the HHRA was that the exposure occurred over a shorter interval (e.g., 2 months in the occupational scenario). Time-averaging the exposure over a 365-day period, rather than over the exposure duration, results in higher calculated PRGs.

- In the HHRA, PRGs were calculated with the EPA ALM using the standard (integrated soil and dust pathway) and discrete soil and dust pathway approaches, however, in the later, a value of 1 was assumed for the soil weighting factor. This assumption effectively converts the discrete approach into the standard approach, since it represents a scenario in which there is no dust ingestion. Thus, the calculated PRGs will always be the same for the two approaches if the values of all other parameters the same.

- The PbB_0 parameter in the EPA ALM was assigned a value of 1.7 µg/dL, a value recommended by the TRW to represent non-Hispanic, white adult females, based on national survey data. The use of 1.7 µg/dL is consistent with TRW recommendations for sites where site data are not adequate to support site-specific estimates of PbB_0. However, the HHRA does not quantitatively explore alternative assumptions that could have been made, given the blood lead data collected at the site.

These topics are discussed in greater detail below.

2.4.1 Use of the EPA ALM for Short-term Exposures

The TRW has recommended a minimum exposure frequency of 1 day per week for a continuous duration of 3 months for applications of the ALM (U.S. EPA, 1996). This recommendation is based on the minimum exposures required to achieve a quasi-steady state blood lead concentration. A quasi-steady state is a required assumption in the methodology because the recommended values for the absorption factor and biokinetic slope factor were based on an analyses of data relating lead exposure to quasi-steady state blood lead concentrations. Furthermore, the relevance of the health criterion10 µg/dL) to short-term exposures is less certain than it is for chronic exposures. ALM-based predictions of adult or fetal blood lead concentrations associated with very short exposure durations or infrequent exposures would be highly uncertain and are discouraged for use in risk assessment. In the HHRA, exposure durations of two months for the occupational scenario do not meet these minimum criteria.

2.4.2 Averaging Time in Relation to Exposure Duration

The averaging time used in the ALM should reflect the exposure duration (U.S. EPA, 1996). This allows for a better assessment of a peak exposure period which may result in adverse health effects, and is more consistent with the biokinetics of lead (deposition and release) in the body. For example, if the assumed exposure season (e.g., warm weather construction season) is considered to be 39 weeks, and the exposure frequency is 5 days per week, or 195 days, a more appropriate averaging time would be 39 weeks x 7 days per week, or 273 days. Similarly, for a short term (3 month) construction project, the concern would be for the peak blood lead achieved during that time period. In this case, 64 day exposure period would be averaged over 90 days. In the HHRA, the averaging time was the number of exposure days per year divided by the number of days in the year. This effectively distributes the lead intake and uptake equally over a one-year period, even when the assumption made in the HHRA was that the exposure occurred over a shorter interval (e.g., 2 months in the occupational scenario). Time-averaging the exposure over a 365-day period, rather than over the exposure duration, results in higher calculated PRGs, which may not provide adequate protection to workers whose activities result in contact with soil.

2.4.3 Use of Soil/Dust Weighting Factor in ALM

The TRW has made recommendations regarding how to use the ALM to calculate PRGs when information is available to quantify discrete intake pathways from soil and dust (U.S. EPA, 1996). The methodology incorporates additional terms for the concentrations of lead in soil and dust (AF_S, AF_D), the mass fraction of soil in dust (K_{SD}), the absorption fraction for ingested dust (AF_D), and the fraction of the total soil plus dust ingestion rate contributed by soil (W_S, soil weighting factor).

In the HHRA, PRGs were calculated using the standard (integrated soil and dust pathway) and discrete soil and dust pathway approaches; however, in the latter, a value of 1 was assumed for the soil weighting factor. This assumption effectively converts the discrete approach into the standard approach, since it represents a scenario in which there is no dust ingestion. Thus, the calculated PRGs will be the same for the two approaches if the values of all other parameters are the same, and therefore, there is no justification for presenting the discrete pathway calculations.

2.4.4 Site-Specific Baseline Blood Lead (PbB_0) in an Uncertainty Analysis

The ALM includes a parameter that represents the blood lead concentration in adults expected at the site if the non-residential soil lead exposure of interest had not occurred. Ideally this should be estimated from blood lead measurements in women of child-bearing age who experience all exposures at the site with the exception of the non-residential exposures of interest, in this case, occupational, and recreational exposures. In reality, obtaining such a sample at a site, and in particular, identifying a representative subset of the population whose blood lead concentrations are not impacted by the non-residential exposures of interest is not always possible. As a result, the PbB_0 parameter is usually assigned a value based on data on other populations, such as national estimates.

In the HHRA, the PbB_0 parameter was assigned a value of 1.7 µg/dL, a value recommended by the TRW to represent non-Hispanic, white adult females, based on national survey data (U.S. EPA, 1996). The use of 1.7 µg/dL is consistent with TRW recommendations for sites where site data are not adequate to support site-specific estimates of PbB_0. However, the HHRA does not quantitatively explore alternative assumptions that could have been made, given the blood lead data collected at the site. As part of the HHRA, blood lead data were collected in 1996 on 667 adults in the CDBA. Based on the population data presented in Table 3-4 of the HHRA, this would appear to represent approximately 16% of the 4200 adults of ages 15-44 years. Table 6-8b indicates that blood lead samples were obtained from 151 women of child-bearing age, defined as 17-45 years of age. If the sex ratio of this age range in the CDAB was approximately 50:50 (see Table 3-4, HHRA), then the sample would represent approximately 7% of the of women of child bearing age in the CDAB (i.e., 151/2100). The HHRA presents the summary statistics of the blood lead concentrations in this group of adult women, and concluded that the geometric means were 2.0 or less in all areas except Burke/Nine Mile (2.4 µg/dL) and Wallace (2.6 µg/dL). Use of the national estimate of 1.7 µg/dL is reasonable in this case because it would be difficult to make a convincing argument that the blood lead sample was representative of women of child bearing age at the site who did not experience soil lead exposures at recreational sites or from occupational activities. Nevertheless, because the geometric mean blood lead concentration of the sample was higher than the national estimate, it would have been informative to explore the implications of a higher site-specific PbB_0 on the estimates of the PRGs as part of the uncertainty assessment. If a site-specific value for PbB_0 were to be used in ALM, it would have been within the range 1.6-2.6. Most of this range would have yielded lower calculated PRGs if used in the ALM in place of the national estimate of 1.7 µg/dL. This would suggest the possibility that the PRGs may need to be lower than those predicted when national estimates of PbB_0 are applied to the site. A similar type of uncertainty assessment could have been applied to the geometric standard deviation (GSD) parameter in the ALM, based on the observed GSD in the sample of women of child bearing age.

2.4.5 Use of Other Input Parameter Values

The construction scenario is usually considered to be a high-end exposure in a risk assessment; therefore, it is usually not necessary to evaluate both central tendency and RME scenarios. However, it is always useful to evaluate the impacts on both the risk and the PRG when the sensitive parameters are varied. These parameters are usually those relating to the intake and to the exposure frequency and duration. In the HHRA, both the ingestion rate and the exposure duration were varied. The TRW has recommended the use of a soil intake in the range of 100 mg/day for a worker with direct contact with soil and dust, however, a range of values could be explored in an uncertainty analysis. However, because the averaging time for a non-carcinogenic contaminant is usually the time over which the exposure occurs, not much change will be seen in risk estimates or the projected PRGs when this parameter is changed. A reasonable scenario that meets the pseudo-steady state criterion and allows evaluation of a range of soil ingestion rates, is probably the most useful, especially in developing a protective PRG for an outdoor worker in the CDAB.

2.5 Assessment of Incremental Lead Intakes and Associated Health Risks to Children

The HHRA includes an assessment of incremental lead intakes and risks associated with recreational exposures of children to lead at neighborhood areas, upland parks and other CUAs (Section 6.6.2, p 6-43, HHRA). The TRW recognizes the importance of evaluating the *incremental* sources of lead exposure that may affect children and adults in the CDAB (e.g., waste piles and contaminated sediments) and supports the HHRA in including these assessments as an important component of the CDAB risk assessment. The HHRA, however, does not clearly indicate how the estimated increments were used in the IEUBK model. The HHRA should more clearly describe that the increments were input in addition to residential sources, and that the incremental blood lead concentration associated with a given recreational activity was (apparently) defined as the difference between the blood lead concentrations predicted when the incremental intakes were included or not included in the model. More importantly, however, the TRW believes that the reported incremental risks of elevated blood lead attributable to recreational exposures may have been underestimated, for several reasons discussed below.

First, exposure estimates for shorter-term exposures should not be averaged over the entire year, for use in the IEUBK Model. The IEUBK model is relevant for continuous exposure periods that are of sufficient duration to produce a quasi-steady state blood lead concentration. The TRW considers the minimum exposure duration to be three months. In order to predict the quasi-steady state that could occur during a shorter (less than a year) period, the soil exposure is not averaged across the year. The HHRA presented a number of assumptions regarding exposure frequencies for these recreational scenarios, which ranged over a period of 168 to 238 days per year. These periods should be long enough to attain a quasi-steady state concentrations if the incidents occur at least once per week.

An additional source of underestimation of risk is use of current environmental lead levels as the baseline for the incremental estimates. Once residences and other frequently used areas are remediated to lower lead concentrations, the incremental risk attributable to exposure at additional recreational areas, if not also remediated, will be greater than suggested in the HHRA, by a substantial amount in some cases.

Another factor qualifying the usefulness of the projected incremental exposures is the appropriate estimates of incremental soil ingestion. The HHRA reported increments estimated from total daily soil ingestion rates reduced by the proportion of waking hours spent at the site. The two components of these increments are the amount of soil ingestion associated with the recreational exposures, and any appropriate weighting. The TRW was not certain whether the intention was to assume that part of the total daily ingestion would occur at the recreational area, or whether the ingestion associated with recreational exposure was expected in addition to typical ingestion rates at more commonly frequented locations (home, school, daycare, etc.). The HHRA calculation resulted in a greater than default amount of daily soil ingestion, which may be quite reasonable. Even higher ingestion may result at a wet site, such as those involving sediments. However, the more representative weighting of soil ingestion is the proportion of <u>outdoor</u> time spent at the site, not the proportion of waking hours.

The approach taken in the HHRA is very similar to that recommended by the TRW, however, the HHRA does not calculate cumulative risks (e.g., P_{10}) associated with the various recreational exposures, but instead, calculates the incremental intakes and incremental central tendency blood lead concentrations. Calculation of the cumulative risks associated with each scenario, or a combination of scenarios would be informative in terms of showing the potential impacts of recreational exposures when combined with residential exposures. This type of analysis is also likely to show that, when recreational exposures are considered, the risk of exceeding a 10 µg/dL blood lead concentration will exceed 5% at all CSUs, when estimated with either the IEUBK default or Box models.

The TRW has made recommendations regarding approaches to utilizing the IEUBK model in assessing cumulative risks from residential and recreational exposures (see Attachment A of this report). This approach was implemented in the risk-based screening assessment of the CUAs in the Lower Basin and a detailed description of the approach is provided in Appendix B of the HHRA.

2.6 Environmental Data Sampling and Quality Assurance

2.6.1 Use of Floor Mats to Collect Residential Dust Samples

A novel feature of the CDAB HHRA was the use of floor mats to collect residential dust samples Section 2.2.1, p. 2-7, HHRA). The dust mat data were not used as input to the IEUBK model runs; dust inputs were derived from vacuum bag samples. The TRW has recommended the use of floor dust samples for estimating house dust lead concentrations and input into the IEUBK model and recognizes that there is very little information available on vacuum cleaner bag samples and floor mat samples and the use of this data in risk estimation at lead sites. However, because the dust mat approach is currently being explored by other researches in the lead field, and because it is an approach that the EPA has no comparable experience, the following observations are offered in this report.

The 1996 sampling event was the first application of door mats for collecting residential indoor dust to assess exposure at a Superfund site. Dust mats were placed in approximately 500 homes in 1996, with no indication of whether vacuum bags and dust mats were collected from the same homes. Vacuum bag samples were collected from approximately 320 homes. Mats were placed inside the home in a *high traffic area* and as close to the main entry as possible. The mats were collected three weeks after placement. Instructions given to the residents of the homes were that the mats should be walked on, but were not to be used as a shoe cleaning mat. If mats were handled in a way that violates the protocol, the mat was excluded from the data set. The HHRA notes that two mats collected in 1999 were excluded from the data analysis. Although vacuum cleaner bag contents were collected, the HHRA does not specify how long the bags were in use, or how such information might have been obtained. It does indicate that efforts were made to verify with the homeowner that the vacuum had not been used outside of the home since previous bag change.

The CDAB HHRA provides comparisons of the dust lead concentrations estimated from the dust mat and vacuum bag samples. Arithmetic and geometric mean dust mat concentrations were higher than vacuum dust concentrations at all of the CSUs. A statistical comparison of the results from the two sampling approaches was not provided in the HHRA. It is unlikely that the unpaired group means presented in the summary tables (Table 6-11 of the HHRA) are significantly different (a paired comparison is not discussed in the HHRA).

2.6.2 Water Sampling

Water samples were collected from homes that were not on community water supplies. In the 1996 sampling event, samples were collected as close to the well head as possible. In subsequent years, flushed and first-draw samples were collected from the tap. The samples collected near the well head may not reflect drinking water exposures. Although this approach to sampling may be useful for detecting potential lead exposures from the water supply, it is not the most desired approach to developing inputs for the drinking water pathway in the IEUBK model because it may not provide a good estimate of actual exposures to children in home. Piping and solder in the home can contribute to lead in tap water. This contribution will vary during the day with use of the home water system, being higher after the water stands for a period and lower after flushing of the pipe system. It will also vary with the hardness or softness, and pH of the water. In order to ensure that this variability is represented in the estimates of drinking water lead concentrations, samples should be collected from the tap of each home, or a representative sample of homes, after the water has been allowed to stand in the pipes (e.g., first flush) and after the pipes have been flushed.

3.0 COMMENTS AND RECOMMENDATIONS IN RESPONSE TO REGION 10 PRIORITY ISSUES

3.1 *Is the risk characterization transparent, clear, consistent, and reasonable?*

The CDAB HHRA is a complex document that demands a careful and thorough reading if it is to be understood in its entirety. This is not surprising given the complexity and history of the site, and the wealth of data that was evaluated in the assessment, including analyses of data from the BHSS. Whether the risk characterization is clear and transparent will be determined only after it has had a wider readership. The sheer complexity of the assessment is likely to result in a wide range of opinions on this, determined, in part, by the background of individual readers and their willingness to give the entire report a complete and thoughtful reading.

From a technical perspective, the TRW found the risk characterization to be consistent and reasonable, in terms of the major outcomes of the assessment. That is, the individual parts of the assessment strongly support the dominant findings that: 1) lead risks to children in the CDAB are unacceptably high; 2) to achieve a reduction of risk to acceptable levels, the site will have to achieve soil lead levels of 400-800 ppm; and 3) the major uncertainties in the latter estimates are the magnitude of the impact of soil lead reductions on house dust lead levels, and the impact of education and intervention on soil and dust ingestion. That an assessment of this complexity can arrive at such a strongly supported set of conclusions, including strong support for a fairly narrow range in the soil clean up level, is remarkable, and a compliment to the architects of and contributors to the assessment.

The HHRA presents the results of three approaches that provide information about lead risk in the CDAB: 1) blood lead screening data gathered over a 4-year period, which may be biased to some unknown degree; 2) the IEUBK default model, which has worked well at other lead sites when data for children who were known to be exposed primarily at their homes were used in the model (Hogan et al. 1998; White et al. 1998), but for which only limited site-specific data to evaluate parameter estimates are available for the CDAB; and 3) IEUBK Box model, which was calibrated to agree with nine years of blood lead survey data, during which environmental and blood lead levels have been decreasing, and for which applicability to the CDAB has not been adequately assessed.

In general, blood lead surveys are the least desirable approach to estimating lead risks, unless the survey is convincingly representative of the population at the site, which does not appear to be the case at the CDAB from the perspective of the TRW. The blood lead screening data for the CDAB do, however, provide important data that show that there is a substantial problem with environmental lead exposures for children in the Basin. In view of the limitations of the blood lead data, many of which are discussed in the Uncertainty Discussion (Section 7.4.1, HHRA), the TRW supports the approach adopted in the HHRA of basing risk estimates on the results of the IEUBK model runs. This approach is consistent with OSWER guidance (U.S. EPA, 1994). Nevertheless, the blood lead measurements and the IEUBK default and Box models yield reasonably consistent information that support the same conclusion, that Basin-wide residential lead risks are above acceptable levels. The blood lead survey indicates that 13% of the screened children between the ages 9-84 months had a blood lead $\geq$10 µg/dL; the IEUBK default and Box models yield P_{10}s of 27% and 10.4%, respectively (for all parts of the Basin combined, 9-84 months). A reasonable estimate of Basin-wide residential risk is within this range and, risks may be higher by 5-10% if incremental risk from recreational exposures are considered. The risk estimates based on default assumptions may be somewhat conservative because of the use of the 175 µm fractions of soil and dust, which may have been enriched in lead relative to the 250 µm fractions that are more commonly measured at CERCLA sites.

This consistency in the outcome of various analyses could be emphasized to a greater extent in the HHRA. Indeed, some readers of the report may be left with a stronger impression of the differences in the outcomes of the three approaches rather than their similarities. The similarities of outcomes are a main strength in the Risk Characterization.

In addition to the above general comments related to consistency and reasonableness, the TRW offers several other suggestions that would strengthen both aspects of the Risk Characterization:

- More emphasis should be placed on estimates of residential lead risk that are based on the batch mode IEUBK model runs, in which risks are estimated at each individual residence, and not on community mode runs. The batch-mode approach is consistent with EPA policy that emphasizes that, for the purpose of supporting remedial decisions for residential contamination, risk assessment approaches should focus on children who receive their principal lead exposures at their homes (U.S. EPA, 1994). The analyses termed “community mode” in the HHRA utilize an inappropriate simplifying assumption that all children within a community are exposed to the same average lead concentrations. The batch-mode is the preferred approach for site assessment, because it ensures that risks at each residence are integrated into the site risk estimate.

- Information that would allow a more complete assessment of the degree to which the blood lead samples reflect the CDAB population would facilitate the interpretation of the blood lead data, particularly the interpretations of comparisons between observed and predicted blood lead concentrations and regression analysis of relationships between exposures and blood lead concentrations. Such information might include the geographic distribution of the sampling within the CDAB and within CSUs, the distribution of response rates across communities, SES scores within the sample compared to those of the CADB and various comparisons of various demographic variables in the sample and CDAB (e.g., age, age of housing, residence time).

- Comparisons between the blood lead concentrations predicted with the IEUBK model and those observed in the CDAB (p. 6-29, HHRA) should not be relied on as the sole basis for evaluating the accuracy of model to represent exposures and blood lead concentrations in the CDAB. In order for this type of comparison to be correctly interpreted, the HHRA would have to provide more evidence that the observed blood lead concentrations adequately represent the CDAB population and that the exposure assumptions adequately represent the individual children sampled. The blood lead comparisons (Appendix Q, Tables Q4.26, HHRA) using alternative assumptions about the dust:soil ratio are useful only as a sensitivity analysis, but not as a basis for adjusting the model, because there is no real basis for attributing a *better fit* between predicted and observed blood lead concentrations to any given variable or set of variables. Also, there is uncertainty regarding factors that may have biased the blood lead observations.

- The IEUBK Box model should not be used as the basis for estimating pre-remediation risks in the CDAB (p. 6-39, HHRA). The Box model was calibrated to agree with the downward trend in post-remediation blood lead concentrations observed at the BHSS. Factors that may have affected this downward trend (e.g., decreased soil and dust intakes resulting from intervention and educational efforts) may not be operating or may not be as important in the CDAB. If adjustments were to be made to the IEUBK model for its application to the CDAB, such adjustments should be based on the available information about exposures and blood lead concentrations in the CDAB. The experience at the BHSS could be applied to the CDAB by gaining a better understanding of the exposure factors that contributed to the downward trend in the blood lead concentrations at the BHSS, and whether or not these same factors can be expected to affect blood lead concentrations in the CDAB to the same degree.

- The concept of separating yard and neighborhood soil contributions to lead intake is a potentially useful one, in particular when applied to predicting the soil lead cleanup levels (p. 6-29, HHRA). If supporting data were available, a similar approach could be extended various potential sources of dust lead exposure. However, Appendix Q of the HHRA does not provide support for use of the 40:30:30 ratio of dust: yard soil: community soil. Appendix Q suggests that there was little difference in predicted blood lead concentrations when either of three dust:soil ratios (55:45, 40:30:30, 75:18:7) were assumed in the model (see Appendix Q, Table 4-26 4-27, HHRA), which leads to an inconsistency in the HHRA.

- In representing the community soil lead levels, the arithmetic mean, rather than the geometric mean is generally preferred (p. 6-39, HHRA).

- The discussion of the bioavailability adjustment in Appendix Q (p. Q-10/2, HHRA) seems to lump the absorption and intake terms in the IEUBK model into a single bioavailability term. These are actually separate parameters in the model that can be affected independently by site factors. Segregating these factors would allow one to consider the potential effects of changes in lead intake or absorption on risk estimates. The assumption that the bioavailability of lead in soil and dust is less than the IEUBK model default model (approximately 30% at low lead intakes) is not adequately justified to support adjustment of the IEUBK model for application to the CDAB (p. 6-39, HHRA). This assumption would be more strongly supported with evidence in animals or humans that the bioavailability of ingested lead in CDAB soil and/or dust is actually lower than the default values or lower than lead in soils from other mining/smelting sites.

- Inclusion of more detailed documentation on the IEUBK model runs would allow the reader to understand exactly how the model was implemented (p. 6-38, HHRA). Ideally, a file containing the inputs to the batch model runs would be important documentation that would enable a third party to reproduce the model runs described in the HHRA.

- The EPA ALM should not be used to estimate PRGs for exposures that are less the three months in duration or less frequent than one exposure episode per week (6-46, Tables 6-57 – 6-60, HHRA). The averaging time used in the EPA ALM should reflect the actual exposure duration.

3.2 *Does the Uncertainty Discussion provide context for the risk results?*

The uncertainty discussion is very comprehensive and does provide excellent context to the risk assessment. However, in some cases, the discussion may be interpreted as being in conflict with the Risk Characterization. For example, the Uncertainty Discussion states that the community-mode IEUBK model runs are of limited value for estimating risks (7.4.4, p 7-39, HHRA) A conclusion with which the TRW concurs. However, risk estimates based on community-mode runs are nevertheless included in the Risk Characterization. The Uncertainty Assessment discusses the limitations in the blood lead data collected in the CDAB and the implications these limitations place on interpreting comparisons with model predictions and in making remedial decisions (Section 7.4.1, p. 7-23, HHRA). However, these data are used in the Risk Characterization, and the outcomes of comparisons with model predictions are described in terms of *over predictions* or *under predictions*, suggesting a greater confidence in the blood lead data than is actually reflected in the Uncertainty Discussion. These inconsistencies are not major problems if the HHRA is thoroughly read and understood, but may lead to misunderstandings or misperceptions for a more casual reader.

The Uncertainty Discussion is largely qualitative and certain conclusions could be more strongly supported by more quantitative sensitivity analyses. For example, certain assumptions for which there is great uncertainty could have been varied in model runs, similar to the approach that was taken in the sensitivity analysis of soil and dist lead levels in the estimate of clean up goals (Section 6.7.6, p. 6-55, HHRA). An example of this is also included in this report as it pertains to the sieving fraction (see attached Figure 1). Assumptions about bioavailability and soil and dust ingestion rates could also have been quantitatively explored. A more quantitative uncertainty analysis, in which the more sensitive model parameters were allowed to vary according to their respective uncertainty ranges, may also have been of added benefit. Such an analysis would have shown, most likely, that the apparent differences in the predictions of the IEUBK default and Box models are actually well within an overlapping range of model predictions, when uncertainty is considered. This would have supported a convergence, rather than a divergence, of the model outcomes. The above suggestions, if feasible, would have complimented the HHRA, but are not needed to support the conclusions of the HHRA or remedial decisions that might follow.

3.3 *Do the predicted house dust concentrations associated with various yard soil action levels support subsequent blood lead predictions and Preliminary Remediation Goals derivations?*

The goal of the approach taken in the HHRA of estimating post-remediation house dust lead concentration from the regression relationship between pre-remediation soil lead and house dust lead is reasonable, given the options available. However, the applicability of the outcome of such an analysis to the post-remediation conditions is uncertain. It should be recognized that when there is substantial noise in the data (e. g., in the lead contamination estimates for specific residences), regression models have a tendency to under-predict the strength of the true relationship between the variables. In this context, it is plausible that cleanup of yard soil will have a larger impact in the reduction of indoor dust levels in residences than is predicted by the regression equations developed in the HHRA. At this point there is insufficient data to determine the magnitude or kinetics of the impact of soil remediation on house dusts at the CDAB site. Numerous factors could result in the post-remediation dust lead levels having a very different relationship to soil lead levels than in the pre-remediation condition.

The dust lead projection will remain an important variable in any projection of post-remediation risks or estimation of clean up levels. This is demonstrated clearly in the sensitivity analysis presented in the HHRA (Section 6.7.6, p. 6-55, HHRA). The effectiveness of soil remediation in lowering blood lead concentrations will depend on the degree to which house dust lead levels decrease in response to changes in soil lead levels. A program in which dust lead levels in the homes were monitored before and after remediation would provide data to develop additional analyses at the site that may allow a more certain quantitation of the impacts of remediation on house dust lead levels.

3.4 *Does discussion of blood sampling methods, participation rates, and age distribution (which changed over time) help to interpret the blood lead screening results?*

The discussion of the blood lead data, in particular, that which appears in the Uncertainty Discussion (Section 7.4.1, HHRA), is very helpful. However, the TRW noted certain details that would have helped if emphasized, but which were absent or difficult to glean from the HHRA. (Ultimately, this information was made available to the TRW via conversations with Region 10).
These include:

- Additional information on the sampling approaches used in 1997 or 1998, for example, the extent to which the sampling was targeted or geographically distributed, would be useful for assessing the representativeness of the data, and whether or not the data should be combined with data collected in other sampling events.

- Additional information on the timing of the blood samples with respect to the timing of environmental samples, noting that all blood lead samples were collected in August and within one or two months of the collection of environmental samples. This is an important positive aspect of the sample design in that it alleviates variables that might otherwise affect interpretations of relationships between the blood lead concentrations and environmental lead levels at individual residences

- Because of the potential effects of health intervention activities in soil and dust ingestion and blood lead concentrations, it would be useful to indicate whether or not blood lead data collected after intervention (e.g,. nurses visits) were used in the various blood lead analyses. As it turns out these data were not used in the risk estimates.

In addition to the above, certain other information and analyses would be helpful, if feasible to provide. These would include the geographic distribution of the sampling within the CDAB and within CSUs, the distribution of response rates across communities, SES scores within the sample compared to those of the CDAB and various comparisons of various demographic variables in the sample and CDAB (e.g., age, age of housing, residence time). Such information might be useful, if available, for exploring further the existence and quantitative significance of biases in the blood lead measurements.

3.5 *Is the discussion of the results from the two modeling approaches sufficient to support risk management decisions protective for human health risks from lead?*

The discussion of the results from the IEUBK default and Box modeling approaches in the batch mode will support risk management decisions. The TRW considers the use of the IEUBK default model to be the preferred approach for decision-making, based on the results of previously reported empirical comparisons (Hogan et al., 1998). These empirical comparisons showed satisfactory agreement between observed blood lead concentrations and IEUBK model predictions for children with environmental lead exposure measurements that characterized the majority of their exposure (approximately 90%-100%), and was relatively stable (that is, not decreasing over time), as the model was designed to be used. This review has discussed a number of reasons why the blood lead data collected in the CDAB, while very helpful for the children surveyed, may not be suitable for calibrating IEUBK predictions for decision-making:

- incomplete information about children's exposures (admittedly, this information is difficult to obtain; typically, about 50% have exposures away from their residences);
- possible enrichment of the residential soil and dust lead concentrations in the 175 µm soil and dust fractions relative to the measurements the IEUBK model was formally calibrated with;
- the non-steady-state nature of the lead contamination, due to on-going clean-up efforts; and
- the on-going community awareness of the lead problem, possibly lowering (temporarily) dust and soil ingestion rates.

The first factor has a unknown impact on the correspondence of observed and predicted blood lead levels, while the last three logically tend toward higher IEUBK predictions relative to observed blood lead levels, due to the design of the IEUBK model. For decision-making, the primary intended use of the IEUBK model, the TRW recommends considering the default dust/soil ingestion rate to estimate risk for future children populations, when environmental lead levels will have finally equilibrated after the last clean-up and behavioral interventions may let up under the presumption that there is no remaining *hazard.*

Nevertheless, the uncertainties discussed in the HHRA and this review argue against completely dismissing risk estimates based on the Box model. Parameter assumptions in the box model are within a range that can reasonably be considered in a sensitivity analysis of IEUBK risk estimates for this site. For the most recent years of data, there are indications that the calibrated (Box) model tends to underestimate some of the risks and that the default model tends to overestimate some risks. In the absence of any strong scientific basis for excluding either model from consideration, the residential clean up levels can be bracketed by using the two models and accounting for 1) recreational exposure-related increments in blood lead, 2) additional uncertainty introduced by the relatively high blood lead concentrations observed in the Lower Basin, given the relatively low soil and dust lead concentrations there; and 3) consideration of the possible effects of lead enrichment in the 175 µm fraction on the risk estimates. These considerations would support a relatively narrow clean up range, for example, 400–800 ppm. The difference between the extremes of the range, although highly significant in terms of potential clean up costs, would be well within the range of uncertainty bounds for each model if uncertainty were to be quantitatively introduced into the modeling results.

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U.S. EPA. 2000. TRW Recommendations for Sampling and Analysis of Soil at Lead [Pb] Sites. U.S. Environmental Protection Agency. Technical Review Workgroup for Lead. April, 2000.

White, P.D., P.V. Leeuwen, B. D. Davis, M. Maddaloni, K.A. Hogan, A. H. Marcus and R.W. Elias. 1998. The conceptual structure of the Integrated Exposure Uptake Biokinetic Model for Lead in Children. Environ. Health Perspect. 106:1513-1530.

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Comments and Responses on:

Public Review Draft
Human Health Risk Assessment for the
Coeur d'Alene Basin Extending from Harrison to
Mullan on the Coeur d'Alene River and Tributaries
Remedial Investigation/Feasibility Study
July 2000

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CONTENTS

SECTION 5.0
STATE/USEPA'S RESPONSES TO INDIVIDUAL COMMENTS

Mining Industry Comments

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
131	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	TG
A1		Hecla Mining and ASARCO	1-Section 1	p.8-25		Not Accepted

Comments>

The HHRA uses a simplistic and generic predictive model and a statistically inadequate set of actual blood lead data to finger soil lead levels in parts of the Basin as a primary source of childhood lead exposure. In so doing, EPA and its contractors ignore the facts that the overall situation in the Basin for children s exposure to lead is a reasonably good one, given the long history of mining and metallurgical activities in the Basin. and that the situation is improving with time. Although the HHRA acknowledges that lead-based paint in aging housing stock and other factors significantly contribute to childhood blood lead levels in the Basin--as well as in urban areas throughout the Nation--the document nonetheless suggests that further soil cleanup in the Basin to levels below the "EPA residential soil screening level of 400 mg/kg" could conceivably be justified. See HHRA at 8-25. The HHRA reaches this ill-supported determination on the basis of blood lead data from a cohort too small to be representative. Moreover, it fails to account for numerous, relevant site-specific factors. As a result, the HHRA fails to recognize that a community health intervention approach in the Basin makes more sense than further extensive soil remediation.

Response>>

The HHRA disagrees with this comment. In comparison to risk assessment methodologies used for other contaminants, the IEUBK is neither simplistic nor generic. The model allows for route specific absorption rates, integrates the effects of lead coming from different routes, and relates the biological response directly to toxicity criteria, on an age-specific basis. This procedure is considerably more complex than that applied in non-lead, non-carcinogenic risk assessment, and results in more precise, and less uncertain, estimates of effects than is typically obtained. As a result, lower margins of safety are employed in sub-chronic lead risk assessment than in the methods used for other metals. Comparison of blood lead data for the Basin to other sites and national or State-wide surveys, for the purpose of determining whether these findings are "relatively good or bad", is problematic. Selection bias may have occurred related to individual family decisions to participate. The HHRA did not draw a conclusion relative to these arguments as there are not sufficient data to test either hypothesis. These opinions are discussed in Sections 6.2.2 and 7.4.1, 8.8, and 8.11.2 and reflect most of the comments offered by reviewers. Community health intervention activities are acknowledged as an effective short-term remedy for children experiencing excess absorption and may have an effect in reducing dose/response in the Basin. However, health intervention is not recognized as a primary prevention remedy under current EPA guidance. Extensive analysis and discussions of site-specific factors are included in the HHRA and the document has been specifically fashioned to provide risk managers with methods to additionally consider site-specific exposure factors. See also General Response to Comments, #9a through #9d and #10a through #10c.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
132	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	TG
A2		Hecla Mining and ASARCO	0-Executive Summary			Not Accepted

Comments>

The HHRA employs EPA's integrated exposure uptake/biokinetic (IEUBK) model as the primary basis for quantifying potential exposures and health risks associated with exposures of young children to lead. The IEUBK model was used to predict children's exposures associated with a baseline residential scenario and with various other potential lead exposure sources, such as recreational contacts with soil, including mine wastes. EPA's guidance for modifying its models, including the IEUBK model, allows only a limited ability to incorporate all of the site-specific environmental data, especially when the environmental conditions vary widely across a large area. The models also do not generally consider other non-environmental factors that influence an individual's health risks. For example, the IEUBK model is very focused on the effect of soil on a predicted blood lead concentration and is not typically used to identify other sources. Incorporation of additional lead exposure from paint, for example, is generally not included because the use of the model to calculate cleanup levels for soil will just indicate that more soil must be remediated to address paint. Care should be taken in selecting input assumptions, however, to make sure that lead concentrations in other media (e.g., indoor dust) are not solely attributed to soil. Such a distinction is generally not made and indoor dust concentrations are automatically assumed to be attributed to soil. The HHRA's approach for application of the lead exposure model is to assume that house dust lead concentrations are due to soil and that paint is not a factor, which is inconsistent with the empirical data.

Response>>

The HHRA disagrees with this comment. In the IEUBK analysis, observed soil and dust lead concentrations are used. No consideration of the source of the lead in dust is inherent in the analysis. The IEUBK is equally capable of predicting the effects of changes along any pathway, and was originally developed to assess required changes in air lead levels, prior to being approved for use in CERCLA and RCRA programs. See also General Response to Comments, #3, #4, and #9.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
133	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	TG
A3		Hecla Mining and ASARCO	0-Executive Summary			Not Accepted

Comments>

The HHRA makes little effort to incorporate site-specific data (other than soil lead and dust mat lead concentrations at house entry ways) for refining the modeling approach. Most importantly, adequate thought is not given to interpreting the modeling results in light of actual observations. EPA and the state have already performed detailed environmental and blood lead studies and a risk assessment within the BHSS that could serve as a useful starting point for the development of site-specific models or interpretation of similar empirical data from the Basin. Rather than serving as a starting point for exposure models for the Basin, the model developed for the BHSS (the "Box model") is used primarily as a point of contrast for the EPA model results based on default inputs. No effort was made to develop a site-specific model for the Basin that would address the differences between the BHSS and the surrounding Basin (e.g., to reflect the lesser importance of smelter emissions outside of the BHSS).

Response>>

The HHRA disagrees with this comment. Site-specific analysis for the Basin was conducted as a major component of the HHRA. Observed soil and dust lead concentrations are used and incremental intakes evaluated are developed on a site-specific basis. See General Response to Comment # A4 and A5. This analysis indicates pathways and dose/response relationships similar to the BHSS for, at least, the upper Basin. As a result, it is not unexpected that the Box Model accurately predicts blood lead levels and percent to exceed the 10 ug/dl criteria for this population, and that the site-specific input values are appropriate. There are questions, however, as to whether the model is representative of members of the population that did not participate in the blood lead surveys. The HHRA was unable to quantify any bias with respect to participation rates and drew no conclusion in regard to this question. See also General Response to Comments, #9a through #9d.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
134	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	TG
A4		Hecla Mining and ASARCO	0-Executive Summary			Not Accepted

Comments>

In the end, neither the Box model nor the EPA default model explains the low average blood lead levels observed within the Basin.

Response>>

The HHRA disagrees with this comment. The Box Model accurately predicts average blood lead levels in the upper Basin and under-predicts average blood lead levels in the Lower Basin.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
135	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	TG
A5		Hecla Mining and ASARCO	0-Executive Summary			Not Accepted

Comments>

In addition, neither of the HHRA models attempts to address the likely variation that exists among the identified exposure areas for site conditions that are likely to affect the IEUBK modeling results (e.g., age of housing, proximity to mine wastes, etc.).
Such critical site-specific issues must be appropriately addressed in the risk analyses so that remediation decisions focus on efforts that will effectively benefit overall public health in addition to meeting the needs of potentially sensitive sub-groups.

Response>>

The HHRA disagrees with this comment. The IEUBK models utilize observed soil and dust lead concentrations that are reflective of the sources on-going for the baseline exposure in the Basin. Incremental exposure assessments are developed in a manner that can be evaluated on a site-specific basis by risk managers. See also General Response to Comments, #3, #4 and #5 .

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
136	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	URS and TG
A6		Hecla Mining and ASARCO	0-Executive Summary			Not Accepted

Comments>

Examples of highly inappropriate modeling assumptions and exposure scenarios and their possible effects on risk management decisions include the following: The soil ingestion rate used for the recreational scenario is greater than that assumed for a reasonable maximum exposure (RME) scenario. The HHRA's soil intake rate for recreational exposure is based on an estimate of the intake for children 1 to 5 years old who are camping in summer, yet this rate is applied to children 4 to 11 years old. Children in this older age group would not have a soil ingestion rate as high as the younger children (consistent with the difference in RME soil ingestion rates for children over 6 years, 100 mg/day, and under 6 years, 200 mg/day). In addition, the types of recreational activities evaluated in the HHRA are daytime activities that would be associated with lower exposure than camping because children would not be living, sleeping and eating outdoors. Unrealistic assumptions about soil ingestion during recreational activities exaggerates the potential risks associated with common-use areas relative to other sources of health risk.

Response>>

Non Lead:

The 300 mg/day value is EPA Region 10's default value for children and adults engaged in intermittent recreational exposures. We used this value for the RME neighborhood scenario's soil and sediment ingestion rates, and it is larger than the RME residential value. The primary references are: (1) the Van Winjen study (1990) based on a 3-5 day exposure study of children aged 0 to 5 years while camping, which provided an upper percentile ingestion rate of 300 mg/day; and (2) a more recent study by Stanek et al (1997) which provides an upper percentile ingestion rate of approximately 300 mg/day for adults engaged in routine day-to-day activities over a 4-week period. Although the Stanek study population was small, its results suggest that adults (and therefore older children) could potentially have upper-bound soil ingestion rates within the vicinity of 300 mg/day. Soil ingestion is likely event-driven and likely occurs at a higher rate during outdoor activities than the average annual value of 200 mg/day. The most important aspect of choosing this contact rate over 200 mg/day is that it represents a short exposure duration in a relatively contact-intensive situation. Thus, this value was deemed appropriate for the 4-11 year old age group for intermittent recreational exposures.

Stanek, EJ III, E Calabrese, R Barnes, and P Pekow. 1991. Soil Ingestion in Adults-Results of a Second Pilot Safety. Ecotoxicology and Environmental Safety. 36:249-257.

Lead:

The HHRA disagrees with this comment. RME ingestion rates are not used in the models. RME rates are provided for risk managers convenience in comparing potential intake rates. See General Response to Comments, #5.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
137	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	URS and TG
A7		Hecla Mining and ASARCO	0-Executive Summary			Not Accepted

Comments>

Examples of highly inappropriate modeling assumptions and exposure scenarios and their possible effects on risk management decisions include the following: The metals concentrations of waste rock piles were used together with other data to compute a community average concentration in soil for use in evaluating recreational exposures of residents and visitors using common areas. The areas where waste piles are present are often distant from residential areas, and the use of waste pile concentrations to predict the average exposure in neighborhood common-use areas misrepresents their potential contribution to recreational exposure. This approach also artificially links elevated blood lead levels to recreational exposure on waste rock piles that, according to Basin residents, is not significant in most areas of the Basin (TerraGraphics 2000).

Response>>

The reviewer is incorrect. Data from waste rock piles were evaluated only for the population of Mullan, Ninemile and Canyon Creeks. The waste pile data included in the HHRA were collected from piles near residential homes. Data from waste piles were analyzed separately - the data were not mixed with other media - and were used to evaluate exposure to children who may play on the piles.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
138	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	TG
A8		Hecla Mining and ASARCO	0-Executive Summary			Not Accepted

Comments>

Examples of highly inappropriate modeling assumptions and exposure scenarios and their possible effects on risk management decisions include the following: Through the exposure assumptions adopted by the HHRA, elevated blood lead levels in Lower Basin children are attributed to their recreational activities in tailings-deposited beaches and other areas distant from their residential yards. However, the blood lead data from this area indicate that children from 1 to 2 years old have the highest blood lead levels of those tested from the Lower Basin. These children are not likely to have significant exposure to sources of lead outside the home or a daycare provider's home/business. If lead sources in common/recreational areas outside the home are the cause of elevated blood lead levels in Lower Basin children, then the older children in this area should have higher blood lead levels relative to those in other areas. In fact, of the 55 blood lead measurements from the Lower Basin, the 3 with results above 15 µg/dL are from children ages 2, 3 and 5. Only 2 of the 27 test results from children who were more than 5 years old had blood lead levels greater 10 µg/dL. Consequently, alternative explanations for elevated blood lead levels should be considered.

Response>>

The HHRA disagrees with the comment. Follow-up information for these 2-5 year old children with high blood lead levels do indicate extended beach and camping activity with their parents in the Lower Basin.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
139	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	TG
A9		Hecla Mining and ASARCO	0-Executive Summary			Not Accepted

Comments>

Examples of highly inappropriate modeling assumptions and exposure scenarios and their possible effects on risk management decisions include the following: Subsistence lifestyles are identified under populations of potential concern. However, there are no individuals, let alone populations, practicing "subsistence lifestyles," as defined by the HHRA, or even relying on the natural resources for the majority of their food. Therefore, this exposure scenario is purely hypothetical, and although it is possible, it is also highly improbable. If risk managers do not realize that this scenario is improbable then they will consider and may recommend costly, large-scale actions directed at calculated exposures and risks. If implemented, such actions may have little effect on actual risks for current or future Basin residents.

Response>>

The HHRA disagrees with the comment. Subsistence scenarios and relevant exposure factors were developed in cooperation with Coeur d'Alene Tribe representatives. The Traditional and Current Subsistence scenarios were requested by the Tribe as representing possible future uses of the area. Exposure factors were derived specifically for the Coeur d'Alene Tribe. Scenarios and exposure factor analysis were patterned after the development of similar scenarios for the Columbia River Tribes used at the Hanford Nuclear reservation. A cultural anthropologist reviewed and suggested appropriate modifications for each of the exposure factors. Each pathway was characterized individually, risk managers can combine pathway results as considered appropriate to estimate total intake rates. No blood lead modeling was performed for subsistence lifestyles. See also General Response to Comments, #6.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
140	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	TG
A10		Hecla Mining and ASARCO	0-Executive Summary			Not Accepted

Comments>

This reliance on hypothetical model results, even where such results are unsupported by empirical observations, is contrary to standard scientific practice in model development and validation and is likely to lead to erroneous remediation decisions that may not effectively benefit public health. The observed discrepancies between the modeling and real-world conditions consists of both over predictions and under predictions, which vary in magnitude and are, in some cases. quite substantial. Such discrepancies indicate that the model structure has failed to adequately characterize those factors determining lead exposure and risk within the Basin. In contrast to the HHRA statements downplaying the importance of empirical observations in assessing potential health risks associated with lead exposures and in making remedial action decisions. such observations are critical for understanding the degree to which the model predictions reflect actual exposures and for identifying the most significant sources of exposure and resulting health risk.

Response>>

The HHRA disagrees with the comment. Site-specific analysis for the Basin was conducted as a major component of the HHRA. Observed blood, soil, paint and dust lead concentrations are analyzed on a home-specific basis. This analysis indicates pathways and dose/response relationships similar to the BHSS for, at least, the upper Basin. As a result, it is not unexpected that the Box Model accurately predicts blood lead levels and percent to exceed the 10 ug/dl criteria for this population, and that the site-specific input values are appropriate. See General Response to Comments, #3 and #9.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
141	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	URS and TG
A11		Hecla Mining and ASARCO	0-Executive Summary			Partially Accepted

Comments>

In summary, the HHRA s inclusion of overly conservative assumptions, improbable exposure scenarios and over-emphasis on negligible sources of exposure (e.g., garden vegetables) results in an inaccurate characterization of existing risks that is of little value for identifying and developing strategies that will be effective in reducing the actual risks.

Response>>

Non-lead:
We disagree that garden vegetables were over-emphasized, particularly for arsenic, see discussion on Page 7-16 and 7-17 of the report which acknowledges the semi-quantitative nature of the vegetable data and recommends further study if risk managers wish to reduce the uncertainty in this area. In addition, the results of the vegetable pathway were not added into the total risk values for residents. However, text will be added to sections 5, 7, and 8 to clarify garden vegetable exposures.

Lead:
The HHRA is a comprehensive evaluation of site-specific information. It includes surveys of a substantial portion of the Basin childhood population, and a review and follow-up identifying individual risk profiles for more than 90% of the children identified with high blood lead levels. The data base contains paired blood lead and environmental exposures for more than 400 observations. Quantitative analysis of this data by regression techniques explain 60% of the variation in observed blood lead levels. In consideration of the well documented individual variance in blood lead levels, this is a strong and compelling finding. The dose response relationships are similar to those based on thousands of observations at the adjacent BHSS. The baseline Box Model developed for the BHSS performs well in predicting both the mean and the distribution of blood lead levels in the upper Basin. Blood lead levels in the Lower Basin are consistent with risk estimates for reported recreational activities noted in the follow up reports. Garden vegetables and other negligible sources are not included in the baseline or recreational blood lead model estimates. See the General Response to Comments for additional details.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
142	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	TG
A12		Hecla Mining and ASARCO	0-Executive Summary			Not Accepted

Comments>

B. Potential for High Bias to Blood Lead Data

The HHRA s discussion of the empirical observations from blood lead and environmental lead concentration data is deficient in a number of respects. The HHRA does not adequately characterize the degree to which these data are representative of the entire area under study. The blood lead concentration results are based on a small sample size. The level of participation is extremely low for accurately characterizing exposure pathways for the entire population in the Basin, especially because the data were not collected using stratified random sampling to attempt to characterize all aspects of the community. The blood lead data are particularly uncertain for some subareas with very low sample sizes (e.g., the Lower Basin).

The HHRA states that there is a 25 percent participation level in the blood lead testing program (based primarily on the 1999 blood lead samples), yet when the data over the four years used in the HHRA are considered, the actual percentage of the population participating is much lower. Since there were 574 blood lead samples from children over the 4 years and all children could have been sampled each year, the eligible population over 4 years is more like four times the 1,100 children per yearly cohort based on the HHRA. The actual participation rate over the 4-year period is more like 574/4400 or less than 15%. The HHRA has not obtained a true “experimental,” i.e., representative, sampling cohort or an observational cohort of sufficient size and participation rate. Consequently, the data may reflect biases introduced by random factors as well as more systematic sampling biases.

Response>>

The HHRA disagrees with the comment. Blood lead levels in the Basin were tested for public health screening purposes to identify children that could benefit from follow-up intervention services. Although it was not collected for purposes for which it is applied in the HHRA, the site-specific blood lead data base is substantial. Appropriate analysis and presentation of this information, in combination with the individual risk profiles developed for high risk children by the local health department and the massive experience at the adjacent BHSS, provides risk managers with insights atypical for a Superfund site. Uncertainty issues associated with these data, analysis and the issues noted in this comment are extensively discussed in Section 7 of the document. The calculation regarding aggrigate screening of children for the four years is incorrect. There are approximately 1,000 children from 9 months through 9 years of age in the Basin. Over 4 years, this group includes about 1,300 individuals, of which 424, or about 1/3 of the population has been screened at least one time. See also General Responses to Comments and response to Comment A13.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
146	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	TG
A13		Hecla Mining and ASARCO	0-Executive Summary			Partially Accepted

Comments>

Due to the low participation in the voluntary blood lead testing program, there are a number of potential biases in these data. Because multiple test results may be included for individual children, then blood lead data may be biased by the presence of repeat tests from families with a child with an elevated blood lead level. These families are more likely to be encouraged to return for retesting by the program operators and may also be more motivated to have the child as well as any siblings retested. Conversely, when a child has a low blood lead level, parents tend to be less concerned and are less likely to bring this child or any siblings in for future testing. Families that may have moved to the Basin from within the BHSS may have also received higher past exposures to lead and may be more inclined to take part in blood lead sampling programs. As noted by the HHRA, the $40 cash incentive in the 1999 monitoring program may have also attracted lower income families. These factors may introduce a high bias to the blood lead data set. In addition, given the small sample sizes from each of the geographic sub areas defined within the Basin, the blood lead data from sub areas may easily be biased by random factors (e.g., many children from one family with high lead exposures). Such biases may inflate estimates of the overall ratio of children with elevated blood lead levels.

Response>>

The HHRA agrees with this comment, but disagrees with the conclusion. Selection bias may have occurred related to individual family decisions to participate. The HHRA did not draw a conclusion relative to the potential biases, as there are insufficient data available to evaluate the question. With regard to repeat testing and siblings, eighty-one (81) children from 57 homes were tested more than once. Sixty-five (65) of those children were tested twice, 13 were tested three times and 3 were tested in each of the four years. Of those children tested more than once, 11 had levels greater than 10 ug/dl and received intervention services from the local public health program. Seven (7) of these children had blood lower blood lead levels in subsequent testing, 1 had the same level, and 3 had higher levels. The children tested more than once tended to have lower than average levels for children in their age group on the first test and similar levels on subsequent testing. These results would indicate that some observations used in the analysis were lower than might be obtained in a random sampling of the population. See also Sections 6.2.2 and 7.4.1, 8.8, and 8.11.2 of the HHRA and General Response to Comments, #2a.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
147	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	TG
A14		Hecla Mining and ASARCO	0-Executive Summary			Partially Accepted

Comments>

In an effort to address these uncertainties, the HHRA suggests that the observed blood lead concentrations are likely to be artificially low because of current community awareness of and efforts to mitigate lead exposures in the neighboring BHSS. The fourth paragraph on page 6-2 notes that site-specific monitoring data accurately describe blood lead levels and that its predictive value for the future may be contingent on continuing public health intervention activities to monitor and reduce blood lead levels. Nevertheless, blood lead monitoring and environmental intervention activities are relatively new to the portions of the Basin outside of the BHSS. Blood lead levels away from the BHSS area of smelter influence have, over the monitoring period from 1996 to 1999, shown no obvious decreases (also stated on page 6-9, fourth paragraph). Blood lead levels during the current economically depressed state of the Basin are actually likely to be worst case and would probably decrease in the future with economic improvement.

Response>>

The HHRA agrees with this comment. Improvement in socio-economic conditions in the Basin would be beneficial to risk reduction programs. See General Response to Comments, #1a.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
148	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	TG
A15		Hecla Mining and ASARCO	0-Executive Summary			Not Accepted

Comments>

C. Preferability of Community Health Intervention Approach

When all of the available information from the Basin is viewed collectively and objectively, other risk reduction strategies, such as community health intervention, education and monitoring programs focusing on individual exposures are clearly more appropriate than extensive further soil excavation. Such programs, and their remediation components, are consistent with EPA's guidance for addressing soil lead hazards attributable to lead-based paint in that they address individual risk factors and focus on significant sources of lead exposure. The existing EPA and HUD guidance (FR Vol. 60, No. 175, 47248-47257) for lead in soil calls for a range of response actions where blood lead levels are elevated and soils have lead concentrations between 400 and 5,000 ppm. The actions range from monitoring and education to a variety of interim physical measures. Soil removal and replacement is not specified as a response action until concentrations are greater than 5,000 ppm (2,000 ppm in recently proposed rule). This guidance recognizes the inherently conservative approach used to identify soil lead hazards as it relates to the cost of soil removal and to the corresponding benefits from reductions in child blood lead levels (i.e., the conservative IEUBK modeling approach used to identify the 400 ppm EPA screening level).

Outreach, intervention, and education programs have proven effective at a number of sites (e.g., Butte, Montana; Leadville, Colorado; and Trail, British Columbia) where they are currently being implemented. These programs may include remediation of soil, as well as other sources of lead, and can be used to target those at risk based on known site-specific risk factors. Educational programs focusing on related health issues such as pre-natal care, nutrition, hygiene and early childhood development may also be instituted. These programs combine intervention efforts for actual lead exposure sources with proactive measures and thereby provide more effective public health protection at lower cost than widespread remedial actions. In the case of the Coeur d'Alene Basin, the mining companies have enlisted the aid of individuals involved with successful intervention programs, as well as recognized experts in the fields of lead toxicology and medicine, to develop a comprehensive program consistent with the "real world data." The Child Health Intervention Program (CHIP) is detailed in the enclosed material. Based on all the existing information, such a program is the most sensible approach for addressing elevated blood leads within the Basin.

As described below, the HHRA offers no adequate empirical basis to recommend disruptive soil excavation and replacement activities over other methods for risk reduction. In fact, the available information supports the type of actions contained in the CHIP. The Basin population has been exposed to multiple sources of lead, including but not limited to mining-related sources, that have been present for at least the last 75 years. Given these long-term conditions, blood lead levels in existing residents provide the best indicator of the baseline health risk from lead and can be especially useful when appropriately paired with environmental lead concentration data for identifying dominant sources of lead exposure. However, when interpreting data for the Basin population to identify sources of lead exposure, it is necessary to recognize the potential for biases in the blood lead data set (see previous comment) and to acknowledge the potential effects

Response>>

The HHRA disagrees with the interpretation of federal guidance. Current directives discourage reliance on behavioral modification programs. Current guidance included in Appendix O states:

"In selecting site management strategies, it is OSWER's preference to seek early risk reduction with a combination of engineering controls (actions which permanently remove or treat contaminants, or create reliable barriers to mitigate the risk of exposure) and non-engineering response actions... As a given project progresses, OSWER's goal should be to reduce reliance on education and intervention programs to mitigate risk. The goal should be cleanup strategies that move away from reliance on long-term changes in community behavior to be protective; behavioral changes may be difficult to maintain over time. The actual remedy selected at each site must be determined by application of the NCP remedy selection criteria to site-specific circumstances. However, this approach recognizes the NCP preference for permanent remedies and emphasizes the use of engineering controls for long-term response actions.…"

Current directives with respect to HUD and TSCA Title IV-403 guidance states: "The TSCA 403 proposed 2,000 ppm hazard level should not be treated as an Applicable or Relevant and Appropriate Requirement (ARAR), "to be considered" or TBC or media cleanup standard (MCS). As recognized in the TSCA 403 rule, lead contamination at levels below 2,000 ppm may pose a serious health risk based upon a site-specific evaluation and may warrant timely response actions. Thus, the 2,000 ppm proposed standard under TSCA 403 should not be used to modify approaches to addressing Brownfields, RCRA sites, National Priority List (NPL) sites, Federal CERCLA removal actions, and CERCLA non-NPL facilities."

Health intervention and behavioral modification programs have been successfully applied to reduce lead exposure reductions. The Lead Health Intervention Program (LHIP) at the BHSS has been found to be an effective interim method to assist parents and principal care-givers in reducing blood levels of children suffering from excess absorption. From 70% to 80% of children with high blood lead levels receiving follow-up services respond positively with reduced blood lead levels. The LHIP has not been demonstrated as an effective substitute for cleanup. Cleanup of active sources, yard soil removals, and the associated reductions in community-wide soil and dust lead levels have been identified as the most effective measures in reducing blood lead level at the BHSS. Implementing a new program or expanding the LHIP over the entire Basin would offer considerable logistic challenges. See also General Response to Comments, #1 and #10.

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type

of diverse residential settings, environmental conditions and family circumstances that exist for that population.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
149	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	TG
A16		Hecla Mining and ASARCO	0-Executive Summary			Not Accepted

Comments>

In an attempt to evaluate community-wide exposures, the HHRA performed multivariate statistical analyses of paired blood lead and environmental lead concentration data to identify significant correlations that may be indicative of an exposure/response relationship. Of the various environmental media examined for correlations with blood lead concentrations, the lead loading rate on entry mats had the highest correlation. Dust on entry mats may originate from both interior and exterior sources as the lead loading rate only describes the amount of dust and not its source. The next highest correlations were observed for various factors for interior or exterior paint condition and interior-paint lead concentration. Interestingly, these variables were more strongly correlated with blood lead level than entry mat dust lead concentration, which indicates that the prior correlation with lead loading is most closely tied to the amount of dust as opposed to the concentration of lead. The effects of housing age and exterior paint condition on blood lead were not examined, and because information on socioeconomic status was not obtained, the effects of this risk factor could not be evaluated for the data set used in the HHRA. However, it is most important to note that yard soil and community soil lead had among the lowest correlations with blood lead. The correlation coefficients reported for soil are low and do not signify "high correlations or strongly correlated" data sets as stated in the text (page 6-20 and page 6-24). Although these results demonstrate that in-home sources of lead, including lead-based paint, can be more significant contributors to blood lead levels than soil, this conclusion was not given adequate consideration when evaluating the risks from lead in soil.

Response>>

The HHRA disagrees with this comment. The analyses referred to were accomplished by stepwise regression where the significance of the variables is determined by entry into, and exit out of the model after accounting for previously selected variables, not correlation coefficients. Dust lead loading is clearly the most significant variable with respect to blood lead levels. With respect to either dust lead loading or dust mat lead concentration, yard soil lead concentration is the most significant source variable. For vacuum bag lead content, dust mat loading is most significant, followed by yard soil lead concentration, and interior maximum XRF paint lead loading. These findings suggest pathway effects similar to those noted at the BHSS and other sites, i.e., soil and paint lead contribute to childhood house dust exposures, with soil lead also acting as an independent source through direct contact. The HHRA concluded that both sources are likely significant, but there is uncertainty regarding paint sources due to the relationship between paint condition and socio-economic status that cannot be unraveled with these data. That conclusion remains unchanged. These findings are consistent with the follow-up reports from public health nurses investigating high blood lead levels and results from other sites including the nearby BHSS. See also General Response to Comments, #1a, #3, #4a and #9.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
150	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	TG
A17		Hecla Mining and ASARCO	0-Executive Summary			Partially Accepted

Comments>

The case-by-case follow-up studies of individual children from the Basin with blood lead concentrations greater than 10 µg/dL also indicate that many factors contribute to the elevated blood lead level (e.g., dusty homes exposure to soil lead concentrations >2,000 ppm, and other sources such as lead-based paint or remodeling exposures). When soil lead concentrations are mentioned as a contributing actor in the follow-up discussions, the concentrations typically are very high (e.g., greater than 2,000, 2,000-3,000, or greater than 4,000 mg/kg). These levels are considerably in excess of those identified later in the report as potential action levels (e.g., 400 to 800 mg/kg). In addition, there is no mention of low socioeconomic status as a risk factor, even though previous reports for this site (IDHW 1999) and the BHSS (TerraGraphics l997) have specifically mentioned the effects of socioeconomic status on blood lead levels.

The IDHW/ATSDR (1999) study of the Basin confirmed that socioeconomic status is an important risk factor for higher blood lead levels in young children. Low socioeconomic status is often related to factors that may increase lead exposure and absorption such as poor home upkeep, nutrition, hygiene, and child supervision. Socioeconomic factors also need to be identified when comparing Basin blood lead statistics to national and state statistics. The only such factor that is tracked in comparisons from the HHRA is age of housing. The relatively high percentage of the Basin population that is considered low income compared to national and state levels is not taken into account. Middle-class to upper-class children in properly renovated old homes are not comparable to the majority of the population in the Basin.

Response>>

The HHRA agrees with this the first part of this comment, but disagrees with the conclusion and mis-characterization of the Basin residents. Exposure to contaminated soils and dusts in excess of 2000 mg/kg lead is a common factor noted in follow-up of lead poisoned children. The HHRA notes in several sections that adverse socio-economic conditions are frequently identified as contributing factors to excess absorption. A discussion of socio-economic status and its relationship to lead poisoning is provided in Section 8.8. Current childhood poverty rates in the Silver Valley are near 30%, about twice the state-wide rate, and certainly not in the majority. Potential lead paint problems are noted for 20 to 25% of the homes, with 2 to 3% exhibiting clearly observable hazards. The majority of families in the area enjoy middle and upper socio-economic status and live in safe and adequate housing. Also see discussion under General Response to Comments, #1.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
151	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	TG
A18		Hecla Mining and ASARCO	0-Executive Summary			Not Accepted

Comments>

Contrary to the available information, only the model applications and conservative inputs support an explanation that soil and house dust containing soil are the primary cause of elevated blood lead levels in children from the Basin. This position is especially difficult to uphold in light of results presented in the 1999 IDHW/ATSDR Environmental Health Exposure Assessment Report that found no significant correlation of blood lead to the concentration of lead in yard soil. The accuracy of this finding has been confirmed by the testimony from government's own expert witness, Dr. Philip Landigran (deposition transcript attached), who stated that the conclusions reached in the IDHW/ATSDR report regarding the lack of correlation between blood lead levels in young children and lead levels in yard soil were accurate.

Response>>

The HHRA disagrees with this comment. The HHRA concluded that contaminated soils, house dust, and lead based paint are all related to excess absorption along complex exposure pathways, with blood lead levels most related to dust lead loading in the home, followed by independent effects of yard soil lead, interior paint lead condition, and exterior paint lead content. The dust lead pathway is most influenced by outdoor soils, augmented by paint contributions in older homes, especially those in poor condition. The conclusions regarding the role and relative importance of contaminated soils and dusts in childhood lead poisoning in the Basin are supported by numerous factors in addition to modeling analysis. Several studies and investigations are cited in the HHRA or support materials for federal guidance have noted similar results. Follow-up investigations by public health personnel have specifically identified soil and dust as the principal source of high blood lead levels observed in children in the Basin and BHSS. More than two decades of information, analysis, and observations at the nearby BHSS have indicated the importance of these sources in children's lead poisoning. Elimination of these sources has been shown to be the principal factor in reducing children's blood lead levels in the last decade. The 1999 IDHW/ATSDR report identifies dust lead loading as that factor most associated with blood lead levels and notes a strong relationship between outdoor soils and dust lead loading. That study also notes that the proportion of children with elevated blood lead levels differed significantly by outdoor playing surface. Thirty-eight percent (37.5%) of children who played outdoors most frequently on dirt or sand surfaces had elevated blood lead levels, compared with 4.8% of children who played outdoors most frequently on grass or other surfaces. These are the same findings that the HHRA indicates. The analysis, results and conclusions of the HHRA and the 1999 IDHW/ATSDR studies are consistent and are in agreement. This is not unexpected, as both studies arise from the same database. The site-specific analysis included in the HHRA employs the same exposure measurements as the IDHW/ATSDR analysis, augmented by quantitative paint exposure estimates and blood lead levels collected from subsequent years from the same homes. See also General Response to Comments, #2, #3, and #4.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
152	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	URS
A19		Hecla Mining and ASARCO	0-Executive Summary			Not Accepted

Comments>

The highest risks identified for non-lead metals are associated with ingestion of soil by children. This result is not unexpected given the high soil ingestion rates used to compute the non-cancer hazard quotients and cancer risks. For the residential scenarios, soil ingestion is assumed to occur year-round (350 days a year), even though the Basin experiences winter conditions and snow cover for months of each year. For the neighborhood recreational scenario, the high soil ingestion rate for 1 to 5 year olds while camping is assumed to occur 1 to 2 times a week for 34 weeks a year, and the high surface water and sediment intakes (via swimming/wading) are assumed to occur 4 times a week for 24 weeks a year. The results of a questionnaire completed by Basin residents regarding their use of recreational areas show that nearly all of the respondents recognized that the soil ingestion rates (computed from the estimated number of days of exposure to soil) and frequencies of exposure to surface water and sediment used by the HHRA were unreasonably high given the local climate.

Response>>

Exposure to soil both by ingestion and dermally continues during the winter inside the home, although likely at a reduced rate, because soil continues to be a component of indoor dust in the winter; however, it is not clear how much reduction would occur. Therefore, the RME scenario did not adjust contact downward for winter while the CT scenario assumed no contact. These two assumptions potentially bound the actual amounts ingested/absorbed. We acknowledge that the exposure frequencies and duration likely overestimate exposure for the majority of recreational receptors; however, 1) information from the Panhandle Health District's lead intervention program indicates that many children do spend very large amounts of time outdoors (12 hours a day for some children), particularly in summer; and 2) the exposure times, in terms of hours per day, are from EPA's 1997 Exposure Factor's Handbook containing national information. Children in the more rural areas of the Basin would be expected to spend more time outside than that estimated from the national information which includes urban children. The RME estimates used in the risk calculations are weighted upwards in part to protect the very high frequency outdoor exposure of some children, and in part to fulfuill the requirements of an HHRA "reasonable maximum" exposure scenario to ensure the public is protected.

Soil residential ingestion rates used in the HHRA are EPAs default values from EPA (1991) Human Health Evaluation Manual, Supplemental Guidance: Standard Default Exposure Factors" (OSWER Dir 9285.6-03). Neighborhood recreational soil ingestion rates are EPA Region 10's default RME value for intermittent recreational exposure. See also response to Comment A6.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
153	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	URS
A20		Hecla Mining and ASARCO	0-Executive Summary			Not Accepted

Comments>

The chronic RfD for lifetime arsenic exposure was used to evaluate the non-cancer risks associated with arsenic ingestion during childhood. A general principal of toxicology is that the dose controls the effect and that the dose is a function of both the amount of daily chemical intake and the length of exposure. Thus, a chemical dose tolerated for a short period of time might cause problems over a longer period of time (chronic exposure) because of cumulative effects. The exposure time for young children is limited to their early childhood (6 years). Reviews of the available data by EPA Region VIII (Benson 1995; 2000) and Exponent (Tsuji et al. 2000) have not found children to be more sensitive than adults to arsenic exposure, except at high doses when acute poisoning occurs. At the lowest doses, the population most at risk is older individuals. Therefore, there is no technical rationale for applying the lifetime chronic RfD to a childhood exposure scenario or for an assumption that children may be more sensitive at low doses than older age groups who have had exposure since birth.

Response>>

The issue of child-specific risk evaluations is an area of ongoing research. While some studies indicate children are not a more sensitive population to arsenic than adults, other studies indicate that they might well be (e.g., Concha et al, 1998 as cited in the NRC report on arsenic in drinking water, 1999). The NRC report concluded that the issue of sensitivity needs more study and in the absence of definitive information, recommended a health-protective approach. We agree and thus did not use the Benson (2000) estimate of a sub-chronic RfD for exposures of less than 10 years. In addition, the Benson (2000) estimate for a subchronic RfD is currently undergoing peer review, and we also considered use of his estimate in advance of peer review to be premature. Therefore, use of the chronic RfD was assumed to be the best available current estimate for use in the child non-cancer calculations. In the absence of peer-reviewed subchronic RfD's, EPA Region 10 (USEPA Region 10, 1999: Region 10 Supplemental Guidance, Assessing Childhood Exposures for Noncarcinogens) policy is to utilize the chronic RfD. Region 10 further states, regarding the use of chronic RfDs for childhood exposures:
"..this risk assessment policy advocates a prudent public health approach of not allowing children's exposures to exceed those allowed for adults when there is no Agency accepted child-specific toxicity value which is specifically developed to be protective of children's health. It's possible that the use of the chronic non-cancer toxicity values may not be protective of children's health. " See also Dr. Paul Mushak's comments regarding the use of the RfD for childhood exposures.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
154	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	URS
A21		Hecla Mining and ASARCO	0-Executive Summary			Not Accepted

Comments>

The estimated cancer risks from arsenic were between 1 x 10-4 and 1 x 10-6 for the child/adult (0 to 30 years) scenario. However, these risks were identified using a linear slope factor to describe the arsenic dose-response relationship, even at low doses. As stated in the HHRA, this approach assumes that there is no threshold for the initiation of toxic effects, such that no dose, no matter how low, is without some risk of cancer. Because the dose-response relationship has not been observed at low doses and is based on extrapolation of high dose observations, the cancer risk predicted for low doses may be grossly over-estimated.

Response>>

We agree that there is some evidence that arsenic-induced carcinogenic responses have a threshold. However, specific modes of action as discussed in EPA's 1996 Cancer Guidelines have not yet been identified for arsenic. Until this occurs we agree with the National Research Council (NRC) recommendation that it is prudent not to rule out the possibility of a linear response.
While a discussion of arsenic toxicity issues is appropriate for the uncertainty section of the risk assessment (which currently notes these issues), evidence is insufficient to change the quantitative calculations and any future risk management decisions based on arsenic. See also Dr. Paul Mushak's comments regarding potential for a threshold response for arsenic.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
155	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	URS
A22		Hecla Mining and ASARCO	0-Executive Summary			Partially Accepted

Comments>

Based on the factors described above, the HHRA's characterization of arsenic risks for the evaluated exposure scenarios very likely over-estimates the potential risks from arsenic exposure in the Basin and could lead to the selection of an overly conservative action level for arsenic in soils. Although risk-based action levels for arsenic are not identified in the HHRA, the draft includes a discussion of the potential for background levels of arsenic to contribute significantly to the arsenic-related health risks described for the Basin. This discussion prompts the question whether the risk assessment methods would identify non-cancer health hazards or unacceptable cancer risks when the arsenic concentrations used in the various exposure scenarios are within the range of background conditions.

Response>>

We agree that risks are likely over-estimated; however, erring on the side of over, rather than under, estimation is necessary to fulfill EPA's mandate to protect human health with an adequate margin of safety. The discussion on Page 7-19 of the HHRA indicates that risks greater than 10E-4 (i.e., "unacceptable") would not occur at background arsenic soil concentrations; however, whether or not there are risks at background concentrations is irrelevant. Superfund cleanups do not address background risks and do not remediate below background levels. Background concentrations and incremental risks above background are taken into consideration when risk management decisions are made.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
156	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	TG
A23		Hecla Mining and ASARCO	2-Section 2	p.2-7		Not Accepted

Comments>

House dust sample collection methodology

An unconventional methodology was used to collect house dust samples. The section on house dust (beginning on page 2-7) notes that vacuum bag samples give a general representation of lead concentration in the home, while dust mats provide lead concentration, dust loading rate and lead loading rate. The text should also clarify that the dust mats were placed just inside the entryway of the home and therefore are representative of dust deposition at the entryway. Collection of dust data from mats in this way differs from the methodology used at most sites to characterize house dust. The dust on a mat just inside an entryway of a home may not accurately reflect indoor dust exposure in a house. The dust mat may be indicative of dirt that is initially tracked in, but it can also contain more lead originating from deteriorating lead-based paint on porches, doors and door frames, which can receive considerable wear. Because many of the homes in the area are quite old, lead-based paint is likely to be present. The lead paint that could have been applied in these high-use areas may also have been a more durable type which historically contained a higher percentage of lead. Similarly, sampling of residents' vacuum bags is also not the most accurate method employed at sites, since the vacuum cleaner can be used on non-living areas such as the car. The preferred method for sampling would be to collect calibrated vacuum floor samples from living areas of the house that are frequented by young children, such as a child's bedroom, the living room and kitchen. This method can give both lead concentration and loading data that are more representative of the indoor dust contacted regularly by the occupants.

Response>>

The HHRA disagrees with this comment. Dust lead exposures were measured by two independent techniques. Samples were collected from home vacuum cleaners, if these were available and had not been used outside or in the family car, and by entryway mats. Both techniques measure lead concentration in the minus 175 micron fraction of dust. This vacuum bag method has also been continuously used in the BHSS since 1974 and has been a significant correlate of both blood lead and soil lead levels. The second technique measures both dust lead concentration from the same size fraction, and the accumulation rate of both dust and lead on the mat. The accumulation rate of lead or lead loading rate on these mats was the single strongest environmental source correlate with blood lead in the site-specific analysis (r=0.634). Both methods have also been employed at socio-economically and demographically similar homes outside the Basin. These results do show that older homes have higher dust lead concentrations and loading rates, but at significantly lower levels than observed in the upper Basin. See also General Response to Comments, #3d.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
157	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	URS and TG
A24		Hecla Mining and ASARCO	2-Section 2	p.2-9		Partially Accepted

Comments>

Waste pile sample collection

Waste piles are coarse-grained, rocky and typically contain few fines. As noted on page 2-9, because of the rocky nature of the waste piles, not enough fines could be collected from the 0- to 1-inch interval for sampling. Instead, samples were collected from the 0- to 6-inch interval and sieved prior to analysis. The difficulty in collecting fines at the exposure point implies that children would have little exposure to fines on waste piles and that the waste pile exposures presented in the HHRA are likely to be over-estimated.

Response>>

Fine material is present in the top inch and this material would stick to children's hands and be ingested; however an insufficient amount was present for laboratory analysis. The assumption is that the concentration found in the 0-6 inch depth is representative of the concentration in the top inch.

Incremental exposures for lead at waste piles do not distinguish among waste pile types and surface characteristics. Incremental intake rates were developed for both members of the population, one for the typical (Central Tendency (CT)) and one for the reasonable maximum exposure (RME). Estimating the intake rates is a relatively straight-forward procedure utilizing exposure factors developed elsewhere in the document. Generally, these factors are linear and intake estimates are proportional to exposure point concentrations, contact times, and exposure frequencies. Should risk managers disagree with the underlying assumptions or wish to consider alternative factors, the incremental intake rates can be adjusted accordingly. This option is discussed in more detail in General Response to Comments, #5a. See also Dr. Muchak's comments on this issue.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
158	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	TG
A25		Hecla Mining and ASARCO	2-Section 2	p.2-5		Accepted

Comments>

Water potato collection methodology

The methodology used to collect samples of water potatoes was not provided in the HHRA. The methodology used by the Coeur d'Alene Tribe to collect and process water potato samples (noted on page 2-5) should be stated in the report or referenced. In particular, the report should identify whether proper chain of custody and quality assurance/quality control (QA/QC) procedures were used. In addition, control samples should have been taken from an area unaffected by tailings to distinguish the incremental amount of exposure due to increased lead in sediments.

Response>>

The HHRA agrees with this comment. The report regarding collection of water potato data will be included in the Appendix of the final HHRA.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
159	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	URS and TG
A26		Hecla Mining and ASARCO	2-Section 2			Partially Accepted

Comments>

Geographic sub-area selection

The selection of geographic sub areas presented in the HHRA does not represent reasonable human exposure potential. Basin geographical sub areas, or conceptual site model units, are introduced in the HHRA in the beginning of this section. These sub areas, however, were selected on the basis of defining the conceptual site model for the Ecological Risk Assessment and are organized based on stream drainage areas and morphology. However, this method of geographical division has little relevance for human exposures. For example, several of the stream segments lack human populations. Also, in some cases, the sub areas encompass unrelated communities on either side of the river. A more appropriate division would focus on communities or populations with similar characteristics.

Response>>

The selection of geographic sub-areas for human health exposure purposes is described in detail in Appendix N. The maps and divisions in Section 2 were intended to provide a transition from the divisions used in the RI and the EcoRA to the HHRA. The divisions used in the HHRA are explained in Section 3. We acknowledge that human exposures would only occur in a portion of the large "exposure areas" identified on the maps in Section 3 and would be centered around homes and recreation areas. In general, the majority of the data used in the HHRA was at or near a home and/or population center and does represent reasonable human exposure potential (see the figures in Section 3). The HHRA identified certain activities that could be "risky" depending on actual concentrations and frequency of use at a specific site, e.g., recreational activities in the Lower Basin. Remedial actions will be made on a home-by-home basis and will not occur without sampling (if there is no data). Common use area remedial activities would be determined on a site-by-site basis and involve the local communities. See also response to Comment B28. The text will be amended to clarify this issue.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
160	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	URS
A27		Hecla Mining and ASARCO	2-Section 2	p.2-15 and p.2-16		Accepted

Comments>

Background concentrations in surface water and groundwater

Background concentrations of surface water and groundwater appear to reflect dissolved concentrations; however, total concentrations were used for site data. Pages 2-15 and 2-16 note that background samples of surface water and groundwater were measured for dissolved metals. If these samples are compared to the site data as total metal concentrations, this comparison represents an inappropriate use of the background data. The total metal concentrations in the background samples are the appropriate data for such comparisons.

Response>>

Background surface water concentrations used in the risk assessment were in fact total concentrations, not dissolved concentrations. The discussion on page 2-15 will be amended to clearly explain this.

The only background groundwater concentrations that were available were for dissolved metals. We agree that comparison of these dissolved concentrations with the total measured concentrations is not appropriate. Therefore, these background values were provided for informational purposes only and are not included on any of the tables or in any of the calculations. This is discussed on page 2-16, but further discussion will be added to clarify this point.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
161	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	URS
A28		Hecla Mining and ASARCO	2-Section 2			Not Accepted

Comments>

Screening arsenic concentrations in surface water

Use of the ambient water quality criteria (AWQC) to screen arsenic concentrations in surface water is highly inaccurate. It should be recognized that very little of the arsenic present in fish is in the form of inorganic arsenic as is assumed by the calculations that underlie the AWQC. The AWQC also incorporates a bioconcentration factor of 44 that is biased upward greatly by considering the bioconcentration factor for bivalves, a factor which was found to be 350 times greater than that for fin fish (USEPA 1980). Since few edible bivalves are available in the Coeur d'Alene River, any calculations of arsenic uptake into edible aquatic organisms should use the bioconcentration factor for fin fish of 1.

Response>>

We acknowledge that the AWQC for arsenic does not represent exposures in the Basin. However, as a screening tool the AWQC is widely used and simply selects arsenic as a chemical of potential concern (COPC). Arsenic would still have been selected as a COPC based on its exceedences over the drinking water Maximum Contaminant Level (MCL) if we had not used the AWQC. The risk calculations assumed a reasonable maximum exposure to surface water while swimming and/or playing in surface water.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
162	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	TG
A29		Hecla Mining and ASARCO	2-Section 2	p.2-6		Accepted

Comments>

Yard soil collection results

Discrepancies were observed in yard soil collection results. Page 2-6 notes that a strong correlation was observed between the results of soil sampling surveys conducted by IDHW together with the Agency for Toxic Substances and Disease Registry (ATSDR) and those conducted by EPA; however, the lead concentrations determined by the EPA protocols may be higher than those observed in the IDHW/ATSDR survey. As a result, the data were combined from the two surveys for all metals except lead. The text should note how lead was handled as a result of this discrepancy.

Response>>

The HHRA agrees with this comment. The combining of soil survey data for HHRA purposes is described in Appendix N. This information will be added to the text in the final HHRA. See also General Response to Comments, #3c.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
163	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	URS
A30		Hecla Mining and ASARCO	0-Executive Summary			Not Accepted

Comments>

Exposure frequency

For arsenic and other metals, 350 days per year of exposure to soil was assumed. Given that the ground surface is frozen and/or snow covered during winter months, this exposure frequency is unrealistically high and should be adjusted to reflect climate conditions in the Coeur d'Alene Basin.

Response>>

See response to Comment A19.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
164	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	URS
A31		Hecla Mining and ASARCO	0-Executive Summary			Not Accepted

Comments>

Soil ingestion rate

The soil ingestion rate used for the recreational scenario is greater than that assumed for an RME scenario. The recreational soil intake rate is assumed to be 300 mg/day which is the 90th percentile for young children ages 1-5 years old while camping in summer (Van Winjen et al. 1990). This rate is assumed for children between the ages of 4 and 11 years for 34 days per year (i.e., once per week for 34 weeks). EPA Region X guidance specifies this rate for recreational activities that might occur for part of a week; during a few weeks of the year because of the lack of averaging over a longer time period. Thirty-four days spread out over April through October from ages 4 to 11 years is a sufficiently long time period for averaging. Children in this older age group would also not have the soil ingestion rate of the 90th percentile of children ages 1-5 years. The RME soil ingestion rate for children older than age 6 is 100 mg/day and for those from 0 to 6 years is 200 mg/day.

Response>>

We acknowledge that EPA's Region 10 guidance memorandum refers to "a few weeks," and that a specific length of time for which the higher ingestion rate should apply is not defined and requires professional judgement. We disagree that the averaging time is sufficiently long to use the average yearly ingestion rate which is based on 350 days per year and selected the more health-protective approach. The days per year of exposure for neighborhood receptors were all less than 10% of the yearly value. Neighborhood park use was assumed to be 34 days per year, waste pile exposure was 17 days per year, and floodplain soil/sediment exposure assumed 21 days per year. See also response to Comment A6.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
165	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	URS
A32		Hecla Mining and ASARCO	0-Executive Summary			Partially Accepted

Comments>

Dermal exposure pathway

Including the dermal pathway in the quantitative risk analyses is unnecessary for metals. Quantitative analyses are unnecessary for the protection of health because the EPA reasonable maximum exposure (RME) assumptions for the soil ingestion pathway are sufficiently conservative to more than adequately make up for the relatively small amount of dermal absorption of metals in soil. Evidence in support of this conclusion includes biomonitoring studies of total inorganic arsenic exposure compared to RME dose calculations via soil ingestion and the low relative bioavailability of arsenic in mine waste via the dermal pathway. Comparison of RME estimates of dose from soil with biomonitoring data from the Tacoma smelter site indicated that the soil ingestion assumptions were consistent with the 95th percentile urinary arsenic value (EPA Region X risk assessment for the Ruston Community; Glass and SAIC, 1992). The urinary arsenic data used in this comparison likely reflected more than soil exposure because these measurements were taken during and shortly after smelter operation when arsenic air levels and dust concentrations were higher. Thus, the RME estimates likely over-estimate actual exposures.

A similar examination for the Anaconda site in Montana also showed that the EPA soil ingestion assumptions for central tendency and RME estimates characterized the majority of urinary levels and the upper percentile levels, respectively, in the community (Walker and Griffin 1998). Calculations for both of these sites also over-estimate the arsenic dose resulting from soil because the amount of exposure due to inorganic arsenic in the diet was not adequately accounted for. Consequently, these studies have not found under-estimation of exposure that might be due to another pathway such as dermal absorption.

Response>>

We acknowledge that there is considerable uncertainty in the dermal pathway. We also note that this pathway is not a risk driver. In the absence of more information, we make the health-protective assumption to consider the potential contribution of the dermal pathway to total risks for arsenic and cadmium. We also acknowledge that the dermal pathway may have been over-estimated for the neighborhood recreational exposures because of the highly conservative estimates of skin surface area. A table will be provided which shows how alterations in skin surface area will affect calculated risks and hazards. See also response to Comment B15.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
166	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	URS
A33		Hecla Mining and ASARCO	3-Section 3	p.3-47		Not Accepted

Comments>

Dermal absorption of arsenic

In the HHRA, the dermal absorption of arsenic from soil is estimated based on data for soluble arsenic. The dermal exposure pathway (page 3-47, fourth paragraph) assumes 3 percent dermal absorption of arsenic based on studies of soluble arsenic freshly added to soil and applied to monkey skin (Wester et al. 1993). As recognized by the detailed discussion on gastrointestinal absorption (next four paragraphs on page 3-47), arsenic in soil from mining sources is likely to be less soluble and to have a lower bioavailability than arsenic from other sources (e.g., 60 percent gastrointestinal bioavailability is assumed as a default value for mining materials versus 80 percent bioavailability assumed as a default gastrointestinal absorption value for arsenic from other sources). At a minimum, the same relative correction factor should be applied to the assumed 3 percent dermal absorption for soluble arsenic (i.e., 0.75, or 0.6/0.8). The resulting absorption factor would be 2.25 percent. This adjusted value is still likely to over-estimate actual dermal absorption for these materials based on the results from human cadaver skin found by Wester et al. (1993) which were lower (0.8 percent) than the in vivo results observed for monkey skin. Because the dermal absorption of arsenic from weathered soil would be less than that from soluble arsenic in soil, the resulting risk estimates are very likely to over-estimate the magnitude of this exposure pathway.

Response>>

We agree that the absorption factor of 3% may overestimate the amount of mining-derived arsenic in soil entering through the skin. However, in the absence of more studies, this value is selected as health-protective. We do not agree that the value should be adjusted by 75%. The 60% factor is from a gastrointestinal absorption study in pigs and it is not known whether gastrointestinal absorption in pigs is comparable to absorption through monkey skin.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
167	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	URS and TG
A34		Hecla Mining and ASARCO	0-Executive Summary			Not Accepted

Comments>

Homegrown vegetable exposure pathway

Ingestion of homegrown vegetables is an exposure pathway of little concern for arsenic and lead and should be excluded from the quantitative risk analyses. Uptake ratios for arsenic and lead into vegetables have been found to be low (Glass and SAIC 1992; ISSI 2000), and biomonitoring data from many sites, including the Basin (IDHW 1999), have not indicated that ingestion of homegrown vegetables contributes to elevated lead and arsenic exposure in residents (Polissar 1987; Polissar et al. 1990; Hwang et al. 1997; University of Cincinnati 1997a,b; Advanced Geoservices 1996; ATSDR 1994; Bornschein et al. 1991; ATSDR 1992; Colorado Department of Health 1994; BSBDH and University of Cincinnati 1992). In fact, IDHW (1999) showed that the Basin residents who consumed vegetables had lower blood lead levels than those who did not. This empirical data contradicts the HHRA risk prediction that nearly all children from all communities would have a blood lead level over 10 µg/dL if they have incremental exposure to lead from homegrown vegetables.

Much of the arsenic in vegetables such as potatoes, tomatoes, carrots, beans and onions is in the relatively non-toxic organic form (Yost et al. 1998; Schoof et al. 1999). Only the percentage of arsenic that is in the inorganic form should be used in calculating health risks using the arsenic toxicity criteria.

Response>>

Arsenic

We agree this is likely not an important pathway for arsenic. However, there is some contribution to total arsenic exposure from the garden pathway and the risk assessment looked at all potential exposures, given the many sources that are present in the Basin, to assist the risk managers in making the most informed decisions. The HHRA noted that the vegetable pathway is semi-quantitative and did not include the calculation results in the total risk and hazard estimates. We acknowledge that arsenic is not 100% in the inorganic form in all foods. However, our reading of the Yost and Schoof papers cited here indicates that 100% of the arsenic in some terrestrial foods could be inorganic and that ranges were 25% to 100%. The Schoof paper concludes that rice and produce are likely to be significant contributors to dietary inorganic arsenic intake. In addition, the work cited in the Schoof and Yost papers was a survey of market produce, not produce grown on arsenic-contaminated soils. The Schoof and Yost papers suffer the shortcomings of the analytical method which was used, where the extraction efficiency (recovery), mass balance and/or integrity of species during sample handling were not evaluated or reported. Controlled experiments indicate that edible produce can accumulate high concentrations of inorganic arsenic when the contaminant is present. In the absence of site-specific speciated data, the 100% assumption is not unreasonable. See also Dr. Paul Mushak's comments on garden vegetable issues.

Lead

"Eating root or leafy vegetables from the household garden or another local garden in the twelve months prior to the study was associated with lower blood lead levels in children less than ten years of age. Better nutrition in this group or socioeconomic factors, such as increased health awareness in the gardening group, may explain this finding. Local vegetables were not tested for lead content in this study" (ATSDR 2000). The HHRA risks were based on samples collected from local gardens and associated intake rates calculated using typical exposure factors.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
168	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	URS
A35		Hecla Mining and ASARCO	0-Executive Summary	p.3-38		Partially Accepted

Comments>

Use of house dust data

House dust data for non-lead metals were ignored and house dust was assumed to be 100 percent soil. Page 3-38 states, "soil is assumed to be a major contributor to indoor concentrations of chemicals in dust. However, yard soil concentrations may be good predictors of some, but not all chemical concentrations in dust." Given that statement, it seems illogical for the calculations in the HHRA to incorporate the assumption that house dust metals concentrations are equal to soil concentrations. Moreover, it is inappropriate for the analyses to be conducted ignoring all of the house dust data for non-lead metals while retaining the house dust data for lead. the metal most likely to have biased house dust data due to non-soil sources (e.g., paint). Data from other sites without active air emissions sources have shown that indoor house dust concentrations for arsenic for example, are lower than outdoor soil concentrations (CDM 1996; University of Cincinnati 1997).

Response>>

We acknowledge that there is uncertainty associated with the assumption that yard soil concentrations are an adequate surrogate for house dust concentrations. We direct your attention to pages 7-14 through 7-16 of the HHRA where this issue is discussed further. The primary reason the data were not used in the risk and hazard calculations was because of the uncertainty of the relationship between soil and dust for the non-lead metals, making a quantitative prediction of dust concentrations where we did not have data highly uncertain. The uncertainty in predicting dust concentrations from soil concentrations was considered more problematic than simply using the soil data. In addition, the majority of risk assessments to date do not have indoor dust concentrations for chemicals other than lead, thus using the soil data as a surrogate has precedence throughout the country. Paired soil and dust data for lead were available for over 800 homes. Therefore, the lead risk assessment, in addition to having a great deal more information for each of the 8 geographic subareas, did not have to predict a relationship in the absence of data. In addition, unlike lead, the soil-dust relationships for other contaminants occurring at sites is not nearly as well understood or characterized. The text will be revised to clarify the non-lead metals dust issues.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
169	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	URS
A36		Hecla Mining and ASARCO	0-Executive Summary			Partially Accepted

Comments>

Combination of exposure parameters

Many of the exposure pathways quantified in the risk assessment include multiple exposure parameters in the risk calculations. In interpreting the results of these calculations, the technical basis and reasonableness of each individual parameter as well as the implications of the combined parameters must be considered. For example, calculations for the dermal exposure pathway for soil and sediment include numerous assumptions including those regarding the frequency of exposure, the potentially exposed skin surface area, the adherence of soil to skin, and the dermal absorption of the chemicals of potential concern (COPCs) from soil or sediment. Using the typical reasonable maximum exposure(RME) approach to such calculations, the combined assumptions for these parameters generally assume that an individual has extensive contact with soil or sediment over the entire possible assumed skin surface area on every day that contact with soil or sediment occurs. The calculations also inherently assume that the soil or sediment remains in contact with the skin sufficiently long for the skin to absorb the entire absorbable fraction of the COPC from the soil or sediment. In actuality, contacts with soil or sediment will vary from event to event. For example, the extent of skin coverage by soil or sediment will differ from event to event, and bathing or other contact with water may remove some or all of the soil or sediment before the entire absorbable fraction has been absorbed.

The combinations of conservative assumptions used to develop exposure scenarios result in even greater over-estimates of actual exposures that are highly improbable. For example, as discussed in more detail below, the combined exposure assumptions for the subsistence exposure scenario yield a total exposure level that is highly unlikely to actually occur. The highly conservative nature of such calculations should be acknowledged in interpreting the risk assessment results.

Response>>

Generally, we agree with the commenters that risks are likely over-estimated. The reasonable maximum scenario (RME) is designed to over estimate risks for most of the population so that any interventions will err on the side of being health protective. While the RME scenarios appropriately use high-end estimates of exposure for many parameters in order to be health protective, some exposure parameters are averages rather than high-end (body weight and skin surface areas). The combination of high-end and average assumptions results in reasonable maximum estimates of health risks.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
170	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	URS and TG
A37		Hecla Mining and ASARCO	0-Executive Summary			Not Accepted

Comments>

Subsistence scenarios

As previously stated in the general comments, inclusion of tribal exposure scenarios that do not presently exist and not are likely to exist in the future is inappropriate for the baseline risk assessment. In addition, both the individual assumptions and the combinations of assumptions used for characterizing tribal exposure are unreasonable. For example, for the traditional scenario, tribal members are assumed to camp on the river all year long and have the following exposures every day of the year from birth to 70 years (except for dirty surface water and sediment exposure as noted):

- Ingest 300 mg/day of soil, which was measured by Van Winjen et al. (1990) as the 90th percentile soil intake rate for 1-5 year old children while camping in summer

- Ingest an additional 300 mg/day of sediment

- For seven months of the year, have the whole body covered with sediment in a layer that is four to eight times thicker (i.e., 0.8 mg/sq.cm) than the amount assumed for the RME residential scenario

- For 365 days per year, have arms, head, forearms, hands, lower legs, and feet of 0-6 year old children covered with soil and have face, hands, and forearms of adults covered also with the thicker layer of soil as assumed for sediment (i.e., 0.8 mg/sq.cm). (This set of unrealistic factors assumes that children wear short sleeve shirts, short pants, and no shoes, even in winter. The total amount of soil and sediment coverage on these exposed surfaces for seven months of the year would be 1.6 mg/sq.cm. The thickness of this layer may exceed the thickness of the monolayer of soil on the skin within which absorption occurs, thus impeding complete chemical absorption from these materials.)

- Drink 30 ml/day of dirty water in the river from freshly kicked up sediments seven months of the year

- Consume their entire vegetable and fruit intake as water potatoes (which may not be peeled) grown in sediment

- Consume 540 g of possibly whole fish (including gills and liver which contain more metals) per day. (This amount is considerably higher than the 170 g/day assumed for the current subsistence scenario, which is based on the 95th percentile consumption rate for four Columbia River tribes. The Coeur d’Alene River is much smaller than the Columbia River and may not support this level of fish intake.)

- Drink 150 percent more surface water from the Coeur d’Alene River than the RME residential consumption rate during every day regardless of season.

Response>>

The HHRA disagrees with this comment. A baseline risk assessment appropriately includes potential future use scenarios. The two subsistence scenarios were requested by the Coeur d'Alene Tribe to represent possible future uses of the area. The specific exposure factors were developed in cooperation with Coeur d'Alene Tribe representatives. A cultural anthropologist, working for the Coeur d'Alene Tribe, reviewed and suggested appropriate modifications for each of the exposure factors. While some of the pathways are likely over-estimated, numerous other potential pathways could not be addressed because of lack of data (see discussion in Section 3.2.4, pages 3-28 - 3-34). See also General Response to Comments, #6.

We refer the commenters to the key study by Harris and Harper in Risk Analysis several years ago, supporting the figure of 300 mg/d for soil, 300 mg for sediment, etc. The paper is:

Ref: Harris SG, Harper BL. A Native American exposure scenario. Risk Analysis 17: 789-795 (1998).

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
171	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	URS and TG
A38		Hecla Mining and ASARCO	0-Executive Summary			Not Accepted

Comments>

Subsistence scenarios

As previously stated in the general comments, inclusion of tribal exposure scenarios that do not presently exist and not are likely to exist in the future is inappropriate for the baseline risk assessment. In addition, both the individual assumptions and the combinations of assumptions used for characterizing tribal exposure are unreasonable. With the exception of the fish and water potato ingestion scenarios, the current subsistence scenario has the same high exposure rates as the traditional scenario except that it assumes 61 days per year of exposure instead of 365 days per year of exposure.

Response>>

We disagree that the exposure assumptions are unreasonable. See response to Comment A37. Note that the differences in exposure duration and fish and water potato ingestion rates between the modern and traditional subsistence scenarios result in risks and hazards that are approximately 80% lower for the modern scenario than for the traditional scenarios. See also General Response to Comments, #6.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
172	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	URS
A39		Hecla Mining and ASARCO	0-Executive Summary			Partially Accepted

Comments>

Combinations of exposure scenarios

The HHRA calculates exposures and risks for a baseline residential exposure scenario as well as for a variety of "incremental" exposure scenarios, e.g., recreational exposure scenarios. The potential exposures and risks for individuals participating in activities covered in different exposure scenarios (e.g., a resident who takes part in the evaluated recreational activities) are then calculated by adding the risk estimates derived for the chosen incremental scenario to those calculated for the baseline scenario. These calculations are not adjusted to account for "double-counting" of exposures, and thus result in over estimates of exposure and risk. For example, when adding a recreational scenario to the residential scenario, the incidental soil ingestion that is assumed to occur as part of the residential exposure scenario is assumed to be unaffected by the additional soil or sediment ingestion that is assumed to occur during the recreational activities. Because some of the incremental exposure scenarios assume relatively frequent and extensive exposures to recreational areas and relatively high contact rates during these activities, it is likely that the baseline residential exposures would decrease if the assumed levels of recreational activity were in fact occurring. Ideally, the results of the risk calculations should be adjusted to account for the double-counting of exposure. The likely over-estimate of risk reflected in the current procedure for combing risk calculations for multiple scenarios must be accounted for when interpreting the risk assessment results.

Response>>

Only the residential and neighborhood recreational scenarios were combined in one table in Section 5 where they were combined in a very qualified manner, primarily to illustrate the potential for additional exposures outside the home, and the potential "double-counting" was acknowledged. They were combined to demonstrate that risks might increase over baseline residential risks if residents also engaged in recreational activities. The last paragraph on page 5-11 acknowledges that the risks calculated from this combination of exposures is likely overestimated because of "double counting". However, more text will be added to clarify this point. See also General Response to Comments, #5.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
173	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	TG
A40		Hecla Mining and ASARCO	0-Executive Summary			Not Accepted

Comments>

Characterization of lead toxicity

In the toxicity profile for lead, as well as elsewhere in the document, the HHRA provides little information regarding how the nature and severity of effects associated with lead exposure vary with the extent of lead exposure.

In fact, as is typical of most dose-response relationships, both the severity of effect and the strength of the evidence linking exposures and effects decrease as the degree of exposure decreases (see, e.g., ATSDR 1999). For example, the cognitive effects of lead are less at lower blood lead levels (e.g., 10-14 µg/dL) than at higher blood lead levels (e.g., 20-30 µg/dL). In addition, the evidence linking low blood lead concentrations and specific adverse effects is weaker than the evidence associated with higher blood lead concentrations (Pocock et al. 1994). Frequently, conclusions regarding the effects of low blood lead concentration are derived from studies of large numbers of children over a range in blood lead levels. Although a linear statistical relationship can sometimes be extrapolated from the blood lead and cognitive test data compiled in such studies, conclusions regarding the potential impacts of low blood lead concentrations are rarely based on empirical observations at those concentrations. As a result, questions exist regarding whether such a relationship exists at low blood lead levels, the form of any such relationship, and the potential persistence of any such effects. Moreover, at low blood lead concentrations, the effects of lead exposure on health endpoints such as cognitive function are difficult to distinguish from the effects of other important influences such as socioeconomic status or nutrition. All of these factors make it important to distinguish between the magnitude of the effects associated with various blood lead levels and exposure durations, and the degree of certainty regarding the likelihood that such effects may occur or persist.

The importance of distinguishing among various lead exposure levels (as reflected in blood lead concentrations) is reflected in the Centers for Disease Control (CDC) guidance for screening children's blood lead concentrations (1991, 1997). This guidance identifies actions required for various blood lead concentration ranges based on the anticipated severity of the health effect as well as the likely effectiveness of the suggested intervention. At low blood lead concentrations in the 10-14 µg/dL range, education and follow-up testing are the primary actions recommended. Characterizing this concentration range as a "border zone," CDC does not recommend other interventions because of concerns regarding the precision of laboratory results at these concentrations and because "it is unlikely that there is a single predominant source of lead exposure for most of these children" with blood lead concentrations in this range. More active interventions such as environmental investigation and lead hazard control are not recommended until blood lead concentrations are in the 20-44 µg/dL range. For children with blood lead concentrations associated with frank and severe toxicity (i.e., >45 µg/dL), active interventions including medical treatment are begun on an urgent basis.

Response>>

The HHRA disagrees with this comment. The comment misrepresent the strength of low-level lead effects as an accepted body of science in the clinical and public health mainstream. A figure or text will be inserted into the final document citing the 1997 and 1991 CDC Statements on lead poisoning in children and the relationships among different blood lead levels and observed health effects.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
174	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	TG
A41		Hecla Mining and ASARCO	0-Executive Summary			Not Accepted

Comments>

For example, the toxicity profile discusses the types of health effects associated with lead exposures in a very general way, providing little information regarding specific blood lead concentrations that have been associated with specific categories or severity of effects.

Response>>

See response to Comment A40.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
175	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	TG
A42		Hecla Mining and ASARCO	0-Executive Summary			Accepted

Comments>

Similarly, the toxicity profile also notes in several cases that no threshold is known for some categories of effects; however, the profile fails to discuss differences in the severity of effects or the strength of the evidence of effects associated with different degrees of exposure.

Response>>

Dose-response relationships for lead will be cited in the final report.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
176	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	TG
A43		Hecla Mining and ASARCO	0-Executive Summary			Accepted

Comments>

The HHRA also includes a number of statements suggesting that serious adverse health effects associated with lead exposure can be associated with “relatively short-term exposures on the order of months.” Again, little context is provided regarding the severity and persistence of the effects associated with various exposure durations. This approach leaves the misleading impression that all of the types of effects discussed in the toxicity profile are associated with lead exposures at any level or for any duration.

Response>>

Effects of lead associated with various exposure durations will also be discussed in the final report.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
177	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	TG
A44		Hecla Mining and ASARCO	0-Executive Summary			Not Accepted

Comments>

The HHRA also discusses the health effects associated with low level lead exposures using terminology that implies that such exposure levels are linked with the more severe effects associated with higher blood lead concentrations. For example, the risk characterization section for lead refers to the analyses conducted in the HHRA (i.e., the evaluations of the potential for blood lead concentrations to exceed 10 µg/dL) as having assessed “[t]he risk of lead poisoning,” a term typically equated in common usage with the more serious effects associated with high level lead exposures.

Response>>

There is a terminology in the HHRA being referred to that is lifted from the 1991 CDC Statement. In the summary portion of that document, lead "poisoning" is noted to not occur below 10 µg/dl. The precise quotation is on p. 3, Table 1-1, "A child in Class I is not considered to be lead-poisoned."

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
178	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	TG
A45		Hecla Mining and ASARCO	0-Executive Summary			Partially Accepted

Comments>

In another portion of the risk characterization discussion, the report uses the term “toxicity rates” to refer to the percentages of children with blood lead concentrations exceeding target blood lead concentrations of 10, 15, or 20 µg/dL. This term has no scientific validity and again provides a misleading perspective on the potential impacts of the blood lead concentration ranges under discussion.

Response>>

This might be confusing terminology, however, again toxicity is referring to "poisoning" as cited in CDC (see Comment A44). There are known health effects associated with certain blood lead levels, which is why the rates or number of children with those blood lead levels is presented. Again, a figure or text will be inserted in the final HHRA showing blood lead levels and the associated health effects; this will help reduce any "...misleading perspectives on the potential impacts of the blood lead concentration ranges under discussion."

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
179	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	TG
A46		Hecla Mining and ASARCO	0-Executive Summary			Accepted

Comments>

To provide more useful information to the community and to risk managers, the HHRA should present information regarding lead toxicity that clearly distinguishes among the types and severity of effects associated with different blood lead concentrations. In particular, the HHRA should present information that is relevant for the types of exposure levels observed in residents of the Basin. This context is necessary to identify the nature of the actual health risks that residents of the Basin may encounter and to make informed decisions regarding appropriate remedial measures.

Response>>

The HHRA agrees with this comment. See response to Comment A40.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
180	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	TG
A47		Hecla Mining and ASARCO	0-Executive Summary			Accepted

Comments>

In addition, the data from the Basin are not completely presented to allow for independent verification of the comparison results or development of alternate analyses.

Response>>

Confidentiality of these data are protected under Idaho State Law. Censored and masked data sets have been developed to release the data in a format that does not compromise individual confidentiality. These data will be included in an Appendix of the final HHRA.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
181	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	TG
A48		Hecla Mining and ASARCO	0-Executive Summary			Partially Accepted

Comments>

Role of socioeconomic status

A factor for socioeconomic status should have been included in the model assessing potential relationships among lead exposure sources. This factor has been shown to be highly significant and well-correlated with blood lead concentrations at this site (IDHW 1999) and others (Succop et al. 1998). This factor is also associated with some of the types of effects associated with elevated lead exposures. The true effect of the various environmental media cannot be identified without correction for socioeconomic status. If a correction factor is not included for socioeconomic status, other factors may become surrogates for this factor. For example, lead loading on dust mats (which is a function of dust loading in addition to lead concentration) may be indicative of home hygiene and house upkeep and age (e.g., older houses have more lead-based paint). Lead in soil and dust is affected by the age and condition of the paint, which are also related to socioeconomic status.

Response>>

The HHRA agrees with this comment. Socio-economic status is an important factor in childhood lead poisoning. However, there is not sufficient data available to include family-specific socio-economic variables in the site-specific analysis. With respect to sources of lead, soil and paint remain the most significant sources manifesting effects through house dust regardless of social status. Socio-economic factors can influence the strength and relative contribution of these sources, contributing to increased media concentrations, ingestion rates, and absorption. See General Response to Comments, #1a.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
182	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	TG
A49		Hecla Mining and ASARCO	6-Section 6	p.6-23, Figure 6-10a		Not Accepted

Comments>

Role of paint

Paint has an important and often hidden influence on dust and soil. Dust mat lead concentration was correlated to yard soil, community geometric mean soil, and paint lead levels. One should recognize, however, that these correlations may be greatly influenced by the effect of eroding paint on soil, house dust, and the dust mat. When an independent variable affects several dependent variables, correlations will appear among the dependent variables. Although yard soil likely affects dust mats and house dust by tracking, the strength of this correlation will be increased by the influence of an independent variable such as paint on both soil and dust. As noted at the end of the first paragraph on page 6-23, homes with poor paint condition also show increased mat dust lead concentrations.

The effect of paint on blood lead levels is a function of the paint concentration and the condition of the paint. Both of these factors need to be combined in the analysis. Thus, although the scatter plots (Figure 6-10a) of paint concentration or condition separately considered relative to concentrations of lead in blood or dust show some variability, it is misleading to conclude that paint has less influence on blood lead levels than other factors. A combined correlation coefficient for the effect of paint concentration and condition should be considered. In addition, the soil concentration near the house (which could affect the dust mat lead concentration) may have been elevated by historical erosion of paint or removal before repainting of the house. Thus, even though the current paint condition may be good, lead paint may be present at the property in the soil and dust. This effect of lead-based paint would not be apparent from the analysis used by the HHRA. Although the HHRA does not show the correlation between paint factors and lead in soil, the summary of the various environmental parameters by geographic sub area indicates that such a correlation may exist.

Given these relationships between lead-based paint, paint condition and dust lead, substantial problems exist in identifying the effects of paint on environmental and blood lead concentrations. It is particularly difficult to evaluate the influence of paint concentrations on the ratio between the lead concentrations in dust and those in soil. As a result, the available data for arsenic or other metals without strong residential sources should be considered as a means for evaluating the relationships between indoor dust and outdoor soil concentrations. CDM (1996) and University of Cincinnati (1997) have noted that arsenic levels are generally lower in indoor dust than in soil relative to lead concentrations. These researchers have also noted that arsenic concentrations show a more accurate relationship between soil that is tracked or blown into the house and yard soil than do lead levels in these media.

Response>>

The HHRA disagrees with this comment. It is important to note that actual observed soil and house dust lead levels were used in both the site-specific and IEUBK model analysis that relate blood lead levels as a dependent variable to environmental dust concentrations. As a result, the sources of lead to soil and dust, such as paint, mineral industry wastes, yard soils, materials tracked in by workers, fugitive dusts, etc. are inherent in the analysis. Dependent blood lead levels are directly related to soils, house dust and other environmental sources as independent variables in either the empirical or mechanistic model derived analysis. Any significant effects in addition to dust from soil or paint are similarly independent and likely represent primary source pathways exclusive of house dust. The result is that lead in soils and dusts represent the primary risk, with house dust being most important to young children. Quantitative analysis of the dust lead pathway in the HHRA concluded dust lead loading is most influenced by outdoor soils, augmented by paint contributions in older homes, especially those in poor condition. The cross product of paint condition and lead concentration was not significant with relation to blood lead levels. Stratification of the database into homes by paint condition yielded insufficient observations to support rigorous analysis, although soil lead remained significant in both subsets. The conclusion of the combined analysis of blood-dust-soils-paint relationship is that, for young children in particular, house dust lead is the primary source of exposure followed by yard soils. Effective risk management strategies need to reduce house dust lead loading. Effectively reducing house dust lead loading requires addressing the principal sources of lead to house dust. Those sources are yard soils, community-wide soils, and paint lead in poor condition homes. These sources also present risk along independent pathways (i.e., direct contact) in addition to their role in dust lead. See also General Response to Comments, #3 and #4.

The HHRA agrees that additional analyses could provide more information for risk managers to consider in developing cleanup strategies. Suggestions were made regarding the inclusion of socio-economic variables and development of paint lead-paint condition interactive factors or cross products in these analysis. However, as was noted for the proposed socio-economic characterization of the blood lead data set, insufficient data are available to perform these adjustments. Suggestions were also made to perform separate analysis of homes with and without paint hazards. This analysis would also be difficult as most homes, other than trailer homes, have lead paint. The primary indicator of paint condition (peeling/chipping/chalking paint) has been shown in the parent 1996 Basin Exposure Study to be highly correlated with home hygiene and socio-economic status. As a result, it is not clear whether the significance of this variable is reflective of the paint source of lead, socio-economic status, personal and family behavior, home hygiene practices, or dust loading.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
183	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	TG
A50		Hecla Mining and ASARCO	6-Section 6	Figure 6-7, Table 6-13		Not Accepted

Comments>

The HHRA also presents a misleading perspective of the paint hazards within the specific geographic sub areas that were evaluated. Specifically, Figures 6-7a,b (Geometric Mean Interior and Exterior Paint Lead Concentration by Geographic Area) provide a misleading representation of potential paint hazards for the Burke/Nine Mile area. This area has the second highest median interior, exterior, and mat location paint concentrations behind Wallace (Table 6-13). Thus, a considerable number of homes in Burke/Nine Mile have elevated lead concentrations in paint. Combined with the likely lower socioeconomic conditions in this area and the dust loading in the homes, elevated blood lead levels here in response to such conditions are not surprising.

Response>>

The HHRA disagrees with this comment. The geometric mean paint lead variable was selected to illustrate paint lead concentrations consistent with the use of geometric means for other media, and was not intended to be misleading. Complete statistical summaries including arithmetic and geometric means, minimums, maximums, and medians are included in Table 6-13 in the HHRA, as noted. Each of these variable forms was included as candidate variables in the step-wise regression analysis.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
184	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	TG
A51		Hecla Mining and ASARCO	0-Executive Summary	p.6-20,6-24		Partially Accepted

Comments>

Correlations between lead concentrations in blood and environmental media

Results presented in the HHRA indicate that the lead loading rate on entry mats had a high correlation with blood lead levels whereas yard soil concentrations had low correlations with blood lead concentrations. Of the various environmental media examined for correlations with blood lead concentrations, the lead-loading rate on dust mats had the highest correlation ($r = 0.63$). The next highest correlations were observed for various factors for interior or exterior paint condition and concentration ($r = 0.34$ to 0.48), followed by mat lead concentration ($r = 0.40$). Yard soil and community soil had among the lowest correlations ($r = 0.16$ and 0.12, respectively). The correlation coefficients for soil and blood cannot be considered "high correlations or strongly correlated" as stated in the text (2nd paragraph, page 6-20; 2nd paragraph, page 6-24).

The more limited contributions of soil lead concentrations to blood lead concentrations are also supported by the analyses of the slope factor relating incremental increases in blood lead concentrations to increases in soil lead concentrations. Specifically, blood lead concentrations were found to increase by 0.7 ug/dL per 1000 mg/kg lead in home yard soil. This effect of soil lead on blood lead is lower than has been observed in the BHSS and at other sites (Succop et al. 1998), and may be suggestive of lower bioavailability of lead in soils in the Basin. This effect of soil on blood lead level is also 10 times lower than the relationship assumed by the IEUBK lead model. For a soil concentration change from 0 to 1,000 mg/kg, this model predicts about a 7 µg/dL change in blood lead and over 17 percent increase in risk of exceeding 10 ug/dL. Thus, the site data are at great variance with the IEUBK model predictions.

Response>>

The HHRA agrees with much of the discussion in this comment, however, there is disagreement with the conclusion. The accumulation rate of lead on entryway mats, or dust lead loading rate, was the single strongest environmental source correlate with blood lead in the site-specific analysis ($r=0.63$). Blood lead is also significantly correlated with median interior and exterior paint lead ($r=0.341$ and 0.407, respectively), yard soil lead concentration ($r=0.158$), and community-wide soil lead concentration ($r=0.116$). With respect to blood lead levels, regression analysis indicated that dust lead loading rate alone explained nearly 40% of the variance in the dependent variable. Other environmental variables were significant in combination with dust lead loading rate. Those variables were yard soil lead levels, median exterior paint XRF reading, and interior paint condition. Comparison of standardized regression coefficients indicate that soil lead and paint have similar effects on blood lead levels, somewhat less than dust lead loading. Both soil and paint, likely, manifest the greatest effect through the house dust pathway. Similar regression analysis indicate that dust lead content on these mats is most related to yard soil lead concentration. The next most significant variable is the community mean soil lead level at the $p=0.0001$ level followed by interior paint lead condition. No other variables are significant at the $p=0.05$ level in the presence of these factors. If community mean soil concentration is eliminated from the selection, the maximum interior paint lead XRF reading and the exterior median paint lead XRF reading are significant at the $p= 0.02$ and 0.03 level, respectively. Vacuum bag lead concentration is related to the mat lead concentration ($p=0.001$), yard soil concentration ($p=0.01$), and maximum interior paint lead XRF reading ($p=0.03$). Vacuum bag lead content typically exhibits about a 30% to 40 % lower concentration than mat lead content. The interpretation of these results in the HHRA was that contaminated soils, house dust, and lead based paint are all related to excess absorption. Overall this suggests complex exposure pathways, with blood lead levels most related to dust lead loading in the home, followed by independent effects of yard soil lead, interior paint lead condition, and exterior paint lead content. The dust lead pathway is most influenced by outdoor soils, augmented by paint contributions in older homes, especially those in poor condition. The slope values for soil and blood level are similar to, but somewhat less than, the BHSS, as noted. These relationships are not inconsistent with IEUBK dose/response relationships as the Box Model has accurately predicted blood lead levels at the BHSS for more than 10 years. These same regression coefficients were used in developing the site-specific parameters for that model. See also General Response to Comments, #7, #8, #9 and Appendix Q of the HHRA.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
185	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	TG
A52		Hecla Mining and ASARCO	0-Executive Summary			Partially Accepted

Comments>

The more limited contributions of soil lead concentrations to blood lead concentrations are also supported by the analyses of the slope factor relating incremental increases in blood lead concentrations to increases in soil lead concentrations. Specifically, blood lead concentrations were found to increase by 0.7 µg/dL per 1000 mg/kg lead in home yard soil. This effect of soil lead on blood lead is lower than has been observed in the BHSS and at other sites (Succop et al. 1998), and may be suggestive of lower bioavailability of lead in soils in the Basin. This effect of soil lead on blood lead is lower than has been observed in the BHSS and at other sites (Succop et al. 1998), and may be suggestive of lower bioavailability of lead in soils in the Basin. This effect of soil on blood lead level is also 10 times lower than the relationship assumed by the IEUBK lead model. For a soil concentration change from 0 to 1,000 mg/kg, this model predicts about a 7 µg/dL change in blood lead and over 17 percent increase in risk of exceeding 10 µg/dl. Thus, the site data are at great variance with the IEUBK model predictions.

Response>>

The HHRA agrees with the statement, but disagrees with the conclusion. The lower blood to soil slope is similar to that obtained at the BHSS and could be indicative of lower bioavailability or reduced ingestion rates. The Box model assumes lower bioavailability, although the discussions, uncertainty analysis, conclusions and qualifiers repeatedly acknowledge that lower ingestion rates associated with ever-present intervention efforts are also a likely explanation of the reduced response rate. However, the comparison of the slope values from the regression and the IEUBK is inappropriate, as it ignores the pathway effects noted in the studies referenced. These soil and dust data applied at 18% effective bioavailibility in the IEUBK model effectively describe observed blood lead levels in both the "Box" and the upper Basin. See also General Response to Comments, #9.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
186	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	TG
A56		Hecla Mining and ASARCO	0-Executive Summary			Not Accepted

Comments>

Geometric standard deviation

The geometric standard deviation (GSD) value is used to estimate the distribution of blood lead concentrations associated with the mean blood lead concentration calculated by the IEUBK model. The GSD is described by EPA as intended to reflect individual variability in blood lead concentrations that might result from a specified level of exposure. The default GSD value used in Version 0.99d of the IEUBK model, however, is based on review of community GSDs reflecting the variability observed in various studies of community blood lead concentrations. Community GSDs tend to be greater than individual GSDs because, in addition to the physiological and biological variability reflected in an individual GSD (e.g., due to differences in lead absorption in different individuals), the community GSD also reflects variability due to differences among individuals in the degree and types of lead exposures that they have (e.g., differing levels of exposure to deteriorated lead-containing paint). As demonstrated in many of the calculations presented in the HHRA and in other analyses (e.g., Bowers 1994), comparisons of predictions of the IEUBK model with observed concentrations in certain communities indicate that the IEUBK model over-estimates the number of children that may exceed a specified target blood lead concentration.

Response>>

The HHRA agrees with much of the discussion in this comment, however, there is disagreement with the conclusion. In the batch mode, the mean and probability to exceed toxicity criteria can also be determined and applied to the individual situation. For the individual situation, the GSD reflects only the inherent variation in response among individuals. The default GSD recommended by the EPA is representative of a number of investigations with varying degrees of exposure variation inherent in results. Applying the typical GSD value of 1.6 to individual situations could overestimate the probability of exceeding 10 ug/dl for the individual. Risk managers may want to consider the application of the 1.6 GSD in the batch mode application as an additional margin of safety when considering the probability of an individual exceeding toxicity criteria. This consideration would not apply to the community-wide estimates of the percent of the community to exceed these criteria. See General Response to Comments, #9c.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
187	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	TG
A57		Hecla Mining and ASARCO	0-Executive Summary			Not Accepted

Comments>

In addition, the default GSD is greater than the community GSDs observed in some communities. For example, at the Sandy and Murray smelter sites in Utah, a GSD of 1.4 was calculated based on site-specific blood lead concentration data (U.S. EPA 1995a, Griffin et al. 1999). Similarly, at the Bingham Creek Channel site, a site-specific GSD of 1.43 was derived (U.S. EPA 1995b). In its evaluations of these sites using Version 0.99d of the IEUBK model, EPA used the site-specific GSDs rather than the default value. These factors suggest that the default GSD represents a conservative estimate of this value and is likely to be one of the reasons that the blood lead concentrations predicted by the model are generally substantially greater than the observed blood lead concentrations.

Response>>

The HHRA notes these observations. However, because the Box Model does accurately predict observed GSDs and the percent to exceed 10 ug/dl, the comment seems superfluous.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
188	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	TG
A58		Hecla Mining and ASARCO	0-Executive Summary			Not Accepted

Comments>

Bioavailability

The EPA default version of the IEUBK modeling presented in the HHRA assumes that the bioavailability of lead in soil and dust is 30 percent, the default model value. This value was modified to 18 percent in the "Box model" version of the IEUBK modeling presented in the HHRA, based on site-specific analyses performed for the BHSS located in the center of the Basin. As discussed in the HHRA, the blood lead concentrations predicted using the Box model (which included other site-specific adjustments) more closely paralleled the observed concentrations than did the concentrations predicted using all default assumptions. This observation suggests that a lower bioavailability assumption may more accurately predict actual lead uptake, at least in some of the modeled exposure areas.

Because the concordance between the modeled and observed results varied from area to area, however, it is likely that the bioavailability of these materials also varies in different areas. Materials that may be present in various portions of the Basin include mine waste from different mines, milling residue, and smelter-derived materials. These materials are likely to differ with regard to several factors that can influence bioavailability such as composition, particle size distribution, and weathering. To make the IEUBK modeling results more useful, differences among the potential exposure sources need to be more carefully examined and incorporated into the modeling efforts. A better understanding of the contributions of various potential sources to total lead exposures will allow remedial decision-making to be more effectively focused on actual exposure sources.

Information from many other mining sites in the Western U.S. indicates that lead forms at these sites are generally lower than the model default (summary by Ruby et al. 1999). Simple, easy-to-use laboratory tests are also available to estimate lead bioavailability in soils. This in vitro method is also showing promising results in comparison with the EPA swine model for measuring bioavailability (Ruby et al. 1999). The systematic determination of bioavailability is strikingly absent from the HHRA and is a significant methodological problem, particularly when mini-dose human assays are available that have been performed on Bunker Hill materials (Maddaloni 1998).

Response>>

The HHRA disagrees with the comment. Although, in-vitro bioavailability data could be a useful addition to the information base considered by risk managers, the laboratory assay has not yet been accepted or validated. Dr. Chris Weis, the EPA PI, has advised against its current application, as the results are still preliminary. No bioavailability data has been collected in the Basin or the BHSS. Please see Appendix O of the HHRA for more information.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
189	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	TG
A59		Hecla Mining and ASARCO	0-Executive Summary			Not Accepted

Comments>

Soil/dust relationship

The IEUBK modeling presented in the HHRA assumes that indoor lead concentrations in dust are due to lead in soil, despite the empirical data shown elsewhere in the report that paint is another contributor to lead in house dust. The report also assumes that the dust mat lead concentrations are equivalent to indoor dust lead concentrations. As noted previously under data collection, dust mat lead concentrations are not necessarily equivalent to indoor house dust concentrations because lead from lead-based paint used on porches, doors and door frames can also be present on entry mats.

Response>>

The HHRA disagrees with this comment. In the IEUBK analysis, observed soil and dust lead concentrations are used. No consideration of the source of the lead in dust is inherent in the analysis. The model uses vacuum dust lead concentrations for house dust input and clearly states that vacuum dust lead levels are typically less than mat concentrations. Vacuum bag lead concentration is related to the mat lead concentration (p=0.001), yard soil concentration (p=0.01), and maximum interior paint lead XRF reading (p=0.03).

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
190	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	TG
A60		Hecla Mining and ASARCO	0-Executive Summary			Not Accepted

Comments>

Dietary lead intake

The default dietary lead intake values applied in the IEUBK model primarily reflect data collected by the U.S. Food and Drug Administration (FDA). Lead levels in food sources have been gradually decreasing over time as a result of various reductions in lead contamination of food, including reductions in the use of lead-containing solder in cans used for food packaging. The default assumptions applied in Version 0.99d of the IEUBK model reflect data collected by FDA during the early 1990s. In a recent application of the IEUBK model, EPA further reduced the dietary intake assumptions to 70 percent of the default values to reflect reductions in dietary lead intake that have likely occurred since the FDA data were collected (Griffin et al. 1999). Because the analyses presented in the HHRA do not account for reduced lead intake from this pathway, use of the default assumptions for this pathway will over-estimate lead exposure and blood lead concentrations. Data published by Manton et al. (2000) also convincingly demonstrated that dietary lead was not a contributor to the measured childhood blood levels. As the BLLs in the Basin continue to fall, the modeled relative contribution of dietary sources becomes more important and leads to further over estimation unless the HHRA continues to "back-titrate" the bioavailability parameter to account for errors in the default entry fields.

Response>>

The HHRA acknowledges the comment, but notes that dietary lead intake ranges from 10% to 20% of estimated total lead intake under current conditions. A thirty percent reduction in dietary intake estimates would have little impact in assessing the baseline situation. The effect, however, could be significant in formulating cleanup criteria, and could be considered a margin of safety for risk managers.

While dietary lead reductions have likely occurred since the data was referenced by the IEUBK, the EPA has not yet recommended how much lead intakes have declined, although the trend of declining dietary lead is generally accepted. The Griffin action has not been reviewed or accepted by the EPA TRW. There have been problems with some recent dietary lead data because non-detects have been reported as zero values in FDA summaries.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
191	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	TG
A61		Hecla Mining and ASARCO	0-Executive Summary			Not Accepted

Comments>

Maternal blood lead concentrations

The default maternal blood lead concentration used in Version 0.99d of the IEUBK model reflects the observed decrease in blood lead concentrations that has been observed in all age ranges of the U.S. population (see, e.g., Pirkle et al. 1994). This decrease has been attributed to the substantial reductions that have occurred in exposures to lead through such previously common lead exposure sources as residential paint, gasoline (and lead-bearing vehicle emissions), and solder used in food storage cans and drinking water pipes. National data indicate that decreases in the blood lead concentrations of women of childbearing age are likely to continue into the future. For example, data from the National Health and Nutrition Examination Surveys (NHANES) reported geometric mean blood lead concentrations in women between the ages of 20 and 49 years of 1.7 µg/dL (for non-Hispanic white women), 2.2 µg/dL (for non-Hispanic black women), and 2.0 µg/dL (for Mexican-American women) (Brody et al. 1994). This comprehensive, national study of a variety of health-related parameters was conducted during 1988 to 1991. For the next younger age range (12-19 years), the geometric means were 1.0, 1.8, and 1.5 µg/dL, respectively. Geometric mean concentrations in the next younger age range (6-11 years) were even lower. These data suggest that as these girls and young women mature, the mean blood lead concentrations in women of childbearing age will continue to decrease. Because this factor was not accounted for in the modeling presented in the HHRA, it again contributes to the over-estimates of blood lead concentrations that are likely to occur using the model default values.

Response>>

It is speculation that women of child bearing age would have decreasing blood lead levels as young women mature, based on the geometric means of these young women. The HHRA agrees that national data indicate decreases in blood lead levels in the past. However, if changes in lead exposure do not change from the group of women of child bearing age and the group of "young women", then it is only speculation that decreases in blood lead levels would be observed in the future. The HHRA used default blood lead levels in the Adult Model, although the average for the women of the Basin in 1996 was 2.0 ug/dl (default value = 1.7 ug/dl). Therefore, this would cause an underestimation of risk for the Basin residents. Please also see General Response to Comments, #11a.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
192	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	URS and TG
A62		Hecla Mining and ASARCO	0-Executive Summary			Partially Accepted

Comments>

Combinations of exposure pathways and scenarios

The exposure and risk calculations include a baseline residential scenario as well as various additional incremental exposure sources (e.g., recreational exposures). As noted previously, the process of combining the baseline and incremental exposures did not include any adjustments to account for double-counting of exposure.

Response>>

The HHRA agrees with the comment. The baseline estimates included in the combined runs are not discounted for the time spent in the incremental behavior. This leads to an overestimation of risk, albeit it small for the current baseline situation. For a child recreational scenario, for example, there would be an unaccounted 5% decrease in time at the baseline residence. The difference in intake would depend on media concentration. Accounting for this reduction in baseline will be important in developing combined residential/recreational clean-up criteria. See also response to Comment A39 and General Response to Comments, #5.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
193	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	TG
A63		Hecla Mining and ASARCO	0-Executive Summary			Not Accepted

Comments>

In addition, some of the combinations presented in the lead analyses appear to mix dissimilar exposure populations without adequately addressing the impacts of such calculations on the assessment results. In particular, the analyses for exposures to waste piles and neighborhood sediments are calculated for children between the ages of 4 and 11 years. The incremental intakes associated with these exposures are compared, however, to the baseline intakes calculated for 4-year-old children using the IEUBK model. Because the baseline intake of lead would be expected to decrease with age, the use of the baseline lead intake of 4-year-old children will over-estimate the baseline intake of children more than 4 years old.

Response>>

The HHRA disagrees with this comment. Four year old intake rates are provided as an example representing the mid-range of age-specific estimates. All IEUBK analysis is performed for age groups 1-7 years of age.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
194	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	TG
A64		Hecla Mining and ASARCO	0-Executive Summary			Partially Accepted

Comments>

In addition, application of the IEUBK model to assess potential lead exposures and blood lead concentrations in children older than the age range included in the model (i.e., 0-6 years) would also tend to over-estimate exposures and blood lead concentrations in the older age range.

Response>>

The HHRA agrees with the comment. IEUBK analysis are conducted for children aged 1-7 years. Risk calculations are pertinent to these age groups. Older children would likely have lower blood lead levels for the same intake rate.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
195	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	TG
A65		Hecla Mining and ASARCO	6-Section 6	Table 6-56b		Not Accepted

Comments>

In some cases, it also appears that the HHRA combines baseline exposures with incremental lead exposures for other activities calculated with RME input parameters (e.g., Table 6-56b). The use of RME parameters is inappropriate for this model, which requires the population's central tendency (geometric mean) and then uses the geometric standard deviation to estimate risks for the upper percentile of the population.

Response>>

The HHRA disagrees with this comment. Extreme responses in the population can be estimated by applying an appropriate GSD to the mean blood lead estimate from the IEUBK model, although this is difficult to interpret as noted. This technique requires that typical, or CT intake rates be input to the model for both the baseline and incremental exposure. The extreme response is estimated by applying the GSD reflect the biokinetic variation in the population and the variation inherent in the typical exposure. However, there are environmental extremes in the potential incremental exposures to consider in addition to the bio-kinetic response and typical baseline exposure factors. Some children, for example, may always play at the most contaminated beaches, rather than at the typical or average concentration. The RME intake estimates, used in the IEUBK estimates in the HHRA reflect CT ingestion rates for both the baseline and incremental exposure applied at 95th percentile contact concentration. See also General Response to Comments, #5.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
196	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	TG
A66		Hecla Mining and ASARCO	0-Executive Summary			Not Accepted

Comments>

Application of adult lead model

The HHRA uses EPA's interim guidance for modeling adult exposures to lead (U.S. EPA 1996). As with the modeling of children's exposures to lead, the analyses for adult exposures to lead presented in the HHRA focus primarily on EPA's default assumptions and do not incorporate site-specific data or considerations. When interpreting the results of the adult model, it should be considered that the model predictions have never been validated against empirical observations. While the individual default assumptions have varying degrees of technical support, the validity of the results yielded by the combined default model assumptions is highly uncertain.

Response>>

See General Response to Comments, #11.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
197	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	TG
A67		Hecla Mining and ASARCO	0-Executive Summary			Not Accepted

Comments>

Absorption fraction of lead from soil

EPA's default soil lead absorption factor (0.12) reflects two components. First, the absorption of soluble lead is assumed to be 20 percent (0.2). Second, the absorption of lead from soil is assumed to be 60 percent (0.6) of the absorption of soluble lead. By multiplying these two factors, an absolute absorption fraction for soil lead of 0.12 is derived. Based on model validation efforts for a physiologically-based model for adult lead uptake, other research has indicated that the mean absorption value for dietary lead sources may be closer to 8 percent (O'Flaherty 1993). Because lead in soil would be expected to be less well absorbed than dietary lead, these data suggest that the typical absorption fraction for lead in soil may be less than 8 percent (i.e., an absorption fraction of 0.08) and less than EPA's default assumption. Results from studies of lead bioavailability from soil using adult volunteers also suggest lower absorption than indicated by EPA's default estimate (Maddaloni et al. 1998). Taking into account the likely relative timing of incidental soil ingestion and consumption of meals, these studies resulted in mean estimates of absorption fraction that ranged from 3 to 14 percent depending on the number of meals assumed to be consumed per day and the assumed soil ingestion pattern.

Response>>

See General Response to Comments, #11 and #9b.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
198	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	TG
A68		Hecla Mining and ASARCO	0-Executive Summary			Not Accepted

Comments>

Geometric standard deviation

As discussed above for the IEUBK model, the GSD is intended to reflect individual variability in blood lead concentrations that might result from a specified degree of exposure. Because data regarding actual GSD values reflecting individual variability are limited for adult populations (as for children), GSD values based on community variability are typically applied to estimate individual variability. Because GSDs for community variability are greater than those reflecting individual variability, use of GSD values reflecting community variability will tend to over-estimate predicted blood lead concentrations at various percentiles for a specified set of exposure conditions.

Response>>

See General Response to Comments, #9c.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
199	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	TG
A69		Hecla Mining and ASARCO	0-Executive Summary			Partially Accepted

Comments>

Timing of exposure

Uncertainty in the results of the adult lead model increases because of the use of the model under some of the exposure circumstances examined in the HHRA. The model is most appropriately applied to evaluate sites under an occupational scenario where it is assumed that adult workers have ongoing, frequent exposures to a relatively constant level of lead in soil. Such conditions would allow lead intake and resulting blood lead concentrations to reach a steady-state condition. Where exposures are infrequent or occur for only a short period of time, the degree of uncertainty in the model predictions increases.

Response>>

Infrequent exposures (i.e., less than 1 day per week) over a minimum duration of 90 days would be expected to produce oscillations in blood lead concentrations associated with the absorption and subsequent clearance of lead from the blood between each exposure event. The TRW recommends that the methodology should not be applied to scenarios in which the exposure factor is less than 1 day/week or less than 3 months in duration (TRW 1996).

The adult recreational scenario in the HHRA uses exposure frequencies equal to 1 full day/week for 15-32 weeks/year (or 105-224 days/year) (Table 6-31). Occupational exposure frequencies used are for 5 days/week for 8.7-39 weeks/year (or 61-273 days/year). The guidance for the Adult Exposures to Lead in Soil model states "...the TRW recommends that this methodology should not be applied to scenarios in which EFs is less than 1 day/week." The adult recreational and occupational RME scenarios used in the HHRA are consistent with guidelines recommended by the TRW and uncertainties associated with the model are discussed in Section 7.0 and more specifically in Section 7.4.4. The occupational CT scenario is less than 3 months in duration and, therefore, will contain more uncertainty. Please see General Response to Comments, #11.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
200	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	TG
A70		Hecla Mining and ASARCO	6-Section 6	p. 6-41 and 6-43		Not Accepted

Comments>

Characterization of modeling results

As previously discussed above, the default model performs particularly poorly in comparison with the empirical data. The evaluation of IEUBK default- and Box-model results (beginning on page 6-41) concludes that the EPA default model consistently overpredicts and the Box model underpredicts the percent of children likely to exceed the 10 µg/dL criteria relative to the empirical data. Whether the Box model overpredicts the observed data, however, depends on the geographic subarea. The default model overpredicts in all areas except Kingston and the Lower Basin. In the Upper Basin, the Box model overpredicts blood lead levels for some subareas and is generally close for the others. The default model highly overpredicts blood lead levels in the Upper Basin. Interestingly, this area has the most paint exposure as well. Without the paint exposure, the empirical data would be even lower than observed, further signifying that both models overpredict exposure.

The poor match in the Lower Basin with the observed data is likely due to the factors mentioned above regarding the sample size in the lower Basin. Also as noted on page 6 43 for the Lower Basin, “A small number of children are exhibiting much greater blood lead levels than expected under any scenario from the Baseline intakes.” These results therefore indicate both models and particularly the default model are not useful for setting remedial goals to address the elevated blood lead levels observed.

Response>>

The HHRA disagrees with this comment. Both the Box Model and the EPA Default Model use observed soil and dust lead levels. Paint contributions are inherent in these input values. Without paint exposure, dust lead levels would be lowered as would predicted blood lead levels. Sample size may be a factor in the Lower Basin, however, baseline blood lead predictions are low because residential soil and dust lead concentrations are low. Both the exposure assessment and follow-up reports of children experiencing high blood lead levels in the Lower Basin identify extended recreational exposures away from the home as probable sources. The baseline IEUBK analysis indicates that residential exposure reductions are called for where soil and dust lead levels are high, and are not necessary where levels are low.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
201	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	TG
A71		Hecla Mining and ASARCO	0-Executive Summary			Not Accepted

Comments>

Other modeling options

Other options for modeling lead exposure exist and should be considered in conducting the analyses for the Basin. In particular, the Integrated Stochastic Exposure (ISE) Model for Lead (Griffin et al. 1999) is similar to the IEUBK model, except that it uses probability density functions rather than point estimates as inputs for most concentrations and exposure parameters. The distributions are combined using Monte Carlo probabilistic techniques to predict a distribution of absorbed doses for different members of the exposed population. The biokinetic portion of the IEUBK model is then used to generate the geometric mean and predicted distribution of blood lead levels rather than applying a single point estimate for the GSD. Unlike the IEUBK model, soil lead concentrations well over 1,000 ppm are required for the predicted greater than 5 percent risk of exceeding a 10 µg/dL blood lead level.

Response>>

The HHRA disagrees with this comment. The IEUBK has been extensively reviewed by the EPA, including reviews by the Science Advisory Board (SAB) in 1991-1992, and subsequent guidance reflecting these reviews was issued approving the IEUBK for sub-chronic risk assessment for lead in children. These guidance documents are provided in Appendix O. None of the other bio-kinetic simulation models suggested by reviewers have been similarly reviewed, nor has any guidance been issued regarding use of these alternate techniques. EPA guidance does recognize site-specific empirical modeling of blood lead levels and dose-response as a useful tool to supplement IEUBK analysis. That analysis was accomplished in the HHRA and is discussed in General Response to Comments, #3, #4, and #9a through #9d.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
202	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	URS
A72		Hecla Mining and ASARCO	0-Executive Summary			Not Accepted

Comments>

Use of chronic RfD to assess childhood risks to arsenic

The chronic RfD for arsenic ingestion is overly conservative to assess childhood risks associated with arsenic ingestion. The chronic RfD is based on a no-effect level in populations exposed to arsenic for most of their lifetimes. Whether the safe dose for children and adults is the same or different depends on whether children are uniquely more sensitive to arsenic than adults.

Reviews of the available studies by EPA Region VIII (Benson 1995) and Exponent (Tsuji et al. 2000) have not found children to be more sensitive than adults except at high doses when acute poisoning occurs. Lower exposure to arsenic appears to delay the onset of health effects such that, at the lowest doses, those showing health effects in populations are not young children, but older individuals. Although few studies have quantified health effects at low doses in very young children, the available studies for children up to 9 to 15 years of age indicates that a no-effect level dose and the RfD for childhood exposure would be higher than that for chronic lifetime exposure. EPA Region VIII (Benson 1995) proposed a subchronic reference dose for children up to 15 years old of 0.006 mg/kg/day, which is 20 times higher than the chronic RfD for arsenic. This subchronic RfD has been used by EPA Region VIII to assess short-term risks to children (ISSI 2000). The subchronic RfD is currently undergoing national review and may be increased from this level depending on the uncertainty factor that is ultimately applied to the no-effect level.

Response>>

EPA Region 10 is awaiting the outcome of the national peer review prior to making any quantitative changes to risk calculations. See also response to Comment A20.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
203	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	URS
A73		Hecla Mining and ASARCO	0-Executive Summary	p.4-6		Partially Accepted

Comments>

Observations of arsenic health effects in U.S. populations

The HHRA fails to adequately acknowledge U.S. data regarding arsenic health risks. U.S. studies have shown few of the health effects associated with arsenic that have been observed in studies of overseas populations. The Utah study cited on page 4-6 of the HHRA (Lewis et al. 1999) found very few significant increases in diseases. The few significant effects found were not among the most noted toxic effects of arsenic and no dose-response relationship was found, which calls into question whether arsenic was the cause. The most prevalent endpoints for arsenic toxicity consistently noted in other studies from foreign countries (i.e., cancers of the skin, lung, and bladder, and effects on the skin) were not found in the Utah population. Because of the large number of disease endpoints examined, the results are also vulnerable to multicomparison errors in which significant associations may result by chance. Prostate cancer, which is common in older men, may also be more prevalent in this Mormon population because of lack of early deaths due to other common diseases associated with smoking and drinking.

Response>>

In the absence of more agreement in the scientific community on these issues, the HHRA takes a health-protective approach. We direct the reviewers attention to papers by Smith and coworkers at Berkeley which include discussions that address the problems with evaluating arsenic health risks in the United States. These researchers have been heavily involved in the epidemiology and biostatistics of population studies of arsenic exposure and mortality/morbidity. The newer citation of Smith et al. that has discussions relevant to this issue are:

Ref: Smith AH, Goycolea M, Haque R, Biggs ML. Marked increase in bladder and lung cancer mortality in a region of northern Chile due to arsenic in drinking water. Am. J. Epidemiol. 147: 660-669 (1998).

See also Dr. Mushak's comments on this issue. We agree with reviewers comments regarding the Lewis study. However, the Lewis data was highly biased against applicability to the general U.S. population. Unlike the Utah study cohort, the U.S. population is largely not Mormon, not as non-smoking, not as non-drinking, not as healthy, in terms of SES and associated health risk factors, potentially all risk factors that affect the expression of adverse effects of contaminants.

An expanded discussion will be added to the uncertainty section on these points.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
204	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	URS
A74		Hecla Mining and ASARCO	4-Section 4	p. 4-7		Not Accepted

Comments>

Risks associated with low dose levels

Arsenic risks at low doses are likely over-estimated by the HHRA. NRC's (1999) conclusion that the arsenic cancer risk at the maximum contaminant level(MCL) in water could be 1 in 100 (see HHRA page 4-7) was not accepted by all authors of this panel. This calculation is very controversial and assumes that arsenic risk can be extrapolated from high doses to low doses below which no effects have been observed. This estimate of 1 in 100 does not consider the findings of EPA's expert review panel on the mechanisms of arsenic carcinogenicity. The findings of this panel were that all possible mechanisms for arsenic carcinogenicity would have a non-linear dose-response relationship (Eastern Research Group 1995). Thus, cancer risks at low doses may well be lower than predicted based on the model used by NRC (1999).

Response>>

We acknowledge that there is disagreement in the scientific community regarding these issues. In the absence of agreement, we chose a health-protective approach. See also response to Comment A21.

We considered the NRC 1999 report as more authoritative on matters of arsenic cancer models than the EPA meeting four years earlier cited by the commenters because the NRC reviewed additional scientific information and all parts of the NRC document underwent peer review. The NRC report considered it prudent not to reject linear low-dose extrapolations for cancer risks from low arsenic intakes. The NRC report made it clear that it considered the nature of the low-dose relationship to be driven by the mechanism of carcinogenic action of arsenic. Since the NRC report appeared, additional data have appeared showing that a linear model at low dose would in fact be reasonable. Mass and coworkers, in work described in an SOT abstract, show that direct interaction of arsenic as the trivalent monomethyl metabolite with DNA was seen in tandem with various measures of DNA damage. Damage included: unwinding (nicking) of DNA and production of double-stranded breaks, and/or induction of alkaline labile sites at levels well below inorganic arsenic levels. A number of other measures of damage were positive. These results show methyl-arsenic (III) being genotoxic via DNA interaction.

Ref: Mass MJ, Tennant A, Roop B, Kundu B, Brock K, Kligerman A, DeMarini D, Wang C, Cullen W, Thomas D, Styblo M. Methylated arsenic (III) species react directly with DNA and are potential proximate or ultimate genotoxic forms of arsenic. The Toxicologist (2001, in press): Proc. Soc Toxicol 40th Annual Meeting, San Francisco, CA, March 25-29, 2001.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
205	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	URS
A75		Hecla Mining and ASARCO	0-Executive Summary			Not Accepted

Comments>

Risk calculations

The documentation of detailed calculations performed to obtain the numerical risk estimates for non-lead metals presented in the document is generally inadequate to perform a thorough review. The specific sets of assumptions and combinations of exposure pathways and scenarios that were used to derive risk estimates are difficult to identify based on the information presented in the HHRA. A more detailed "road map" of the calculations performed to support the risk assessment should be provided in the documentation.

Response>>

We are uncertain as to what additional information the reviewers suggest should be provided. Section 3 discusses in depth the processes and equations used to calculate chemical intakes and provides tables of all input parameters used. Section 4, Table 4-1, provides the toxicity criteria used in the risk calculations and Section 5 discusses in depth the process and equations used to calculate risks. Appendix A contains EPA's RAGS Part D tables which walk someone through all steps to each calculation completed in the HHRA. Appendices E and F provide the raw data and summary statistics that were used to calculate the exposure point concentrations (EPCs).

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
206	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	URS
A76		Hecla Mining and ASARCO	0-Executive Summary			Partially Accepted

Comments>

Risk characterization results

The results of the risk calculations for the non-lead chemicals provide a misleading perspective on the degree of risk associated with exposures to these COPCs at this site. As noted above, the conservative nature of many of the individual exposure assumptions and the combinations of exposure pathways and scenarios yield highly conservative estimates of the potential risks associated with the site.

Response>>

As noted in earlier responses, RME risk estimates are intended to over-estimate risks, i.e., be a "reasonable maximum" in order to be health protective. The Central Tendency (CT) risks are intended to represent a more average situation and CT risks are also presented and discussed in Section 5. Text will be added to expand the CT results discussion. See previous comments on this issue, A39 and A36.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
207	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	URS
A77		Hecla Mining and ASARCO	0-Executive Summary			Partially Accepted

Comments>

The total hazard index for all metals over-estimates non-cancer risk because the effects of these metals are not likely to be additive. Non-cancer hazard quotients added over pathways and constituents are not likely to be additive. In fact, several of these metals are likely to compete for absorption in the gastrointestinal tract thereby reducing their combined toxicity. For example, iron and zinc are well known to antagonize the absorption and effects of other metals.

Response>>

We agree that iron and zinc are well known to antagonize the effects of other metals and this issue is discussed specifically in the HHRA on pages 5-4, 7-20, and 7-21. We acknowledge that the focus of subsequent discussions in Section 5 stills assumes additivity. However, some individual effects from COPC metals may be additive. Additivity or its rejection requires knowledge of the mechanisms of toxic action for these Basin contaminants. Toxic action mechanisms have not been fully characterized for all COPCs; thus knowledge to reject inter-organ or inter-tissue toxic interactions is not currently available. However, we will add more discussion to Section 5 concerning what the hazards would be if additivity is not assumed..

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
208	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	URS
A78		Hecla Mining and ASARCO	0-Executive Summary			Not Accepted

Comments>

Non-cancer and cancer risks for soil are highest for the child scenario because of the conservative approach of combining the chronic RfD for arsenic ingestion with high childhood doses. As noted above, an RfD that is more appropriate for assessing childhood non-cancer risks should be used rather than the chronic reference dose. Non-cancer hazards of arsenic for chronic 30-year exposure duration are a low concern.

Response>>

See previous response to Comment A20.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
209	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	URS
A79		Hecla Mining and ASARCO	0-Executive Summary			Partially Accepted

Comments>

Subsistence risks are greatly over-estimated. As described above, subsistence populations are assumed to eat a high amount of soil and sediment, to be completely covered over their whole body with a coating of sediment for seven months of the year and an additional coating of soil on exposed parts of the body for 365 days per year, and to drink 150 percent of the RME water ingestion rate from the river. It is not surprising that such assumptions led to dermal absorption, soil/sediment ingestion, and water ingestion being among the exposure pathways that contributed the most to a total cancer risk for this scenario of 4 x 10-3. This scenario combines so many worst-case and improbable assumptions, however, that the calculated risks have little relevance for risk management decisions.

Response>>

See response to Comment A37 and General Response to Comments, #6.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
210	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	URS
A80		Hecla Mining and ASARCO	0-Executive Summary			Accepted

Comments>

Presentation of results

Given the number of individual risk calculations and combinations of calculations provided in the HHRA, clear and consistent presentation of the risk calculation results is essential to aid review and synthesis of the results. In any risk characterization, it is important to present the numerical results; provide benchmarks for interpreting the results (e.g., target risk levels); identify primary chemicals, exposure pathways, and scenarios contributing to total exposures; and discuss major factors influencing the uncertainty of risk assessment results. While these issues were generally addressed in the risk characterization and summary sections of the HHRA, they were not always addressed in a consistent way. In particular, in the summary section of the report, the discussion of the cancer risk assessment results clearly identified those risk estimates that exceeded EPA's acceptable risk range. For risk estimates that did not exceed the range, however, the comparison with the risk range was not always discussed. Instead, the summary of these pathways frequently focused on those subcomponents of the total risk estimate that were associated with the highest risk or that were the primary contributors to risks. This approach gives the misleading impression that all of the exposure pathways and scenarios were associated with elevated and unacceptable risk levels.

Response>>

Comment noted. This section will be revised as appropriate to provide more consistency.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
211	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		0/30/2000	URS
A81		Hecla Mining and ASARCO	0-Executive Summary			Accepted

Comments>

Similarly, the summary of the non-cancer risk assessment results highlighted potentially unacceptable risk estimates in a misleading way. Specifically, the presentation of the hazard indices began with a review of the results obtained by combining the hazard quotients for all COPCs, regardless of health endpoint of concern. Such an approach is only to be used as an initial screening analysis and should have been clearly identified as such at the beginning of the discussion of these results. Only after an extensive discussion of the total hazard indices, the HHRA presented a limited discussion of the technical deficiencies in such an approach, particularly for the risk analyses for the Basin where there is limited overlap in health endpoints among the COPCs. This subsequent discussion then noted briefly that some of the hazard indices identified as exceeding the target level in the initial analyses would not, in fact, exceed the target when the more technically appropriate approach was used.

Response>>

Comment noted, see response to Comment A77. We will provide additional discussion regarding the hazard results if additivity is not assumed.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
313	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		1/02/2000	TG
A82		Hecla Mining and ASARCO	2-Section 2	p.2-7		Partially Accepted

Comments>

Soil samples were also sieved to particle sizes <175 µm prior to sampling which, as noted on page 2-7, is a smaller size fraction than the fraction sampled for the calibration of EPA's IEUBK model for lead. This would tend to bias the sample concentration result upward with respect to the size fraction that is typically incorporated into IEUBK modeling. This size fraction (<175 µm) is also not the standard for assessing bioavailability of metals in soil (I.e., <250 µm, Ruby et al. 1999).

Response>>

The HHRA agrees with this comment. The 175 micron mesh sieve technique was adopted in 1974 for the original lead health studies conducted in the area and has been used for all residential soil samples collected in the Basin RI/FS and all previous health and exposure studies. The procedure was developed to reflect the range of soil particle sizes that most likely adhere to children's hands which are then transferred by hand-to-mouth activities. Subsequent research has continued to show that this size-range is applicable. The selection of this standard pre-dates either recommendation from federal agencies, and the State Department of Health and Welfare has elected to maintain consistent soil and dust measurement techniques throughout the course of these investigations. The EPA has concurred in that determination. Assuming any concentration effect due to sieving is proportional, the use of a lower value (as suggested might occur with EPA's larger sieve size) would result in an increased dose response coefficient in the site-specific analysis. That is, the per unit effect of soil or dust lead concentration on blood lead levels would be greater. This would be interpreted as indicating higher bioavailability of soil and dust or lesser intake is occurring in the population. See also General Response to Comments, #3c and #9b.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
314	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		1/02/2000	URS
A83		Hecla Mining and ASARCO	2-Section 2	p.2-10		Not Accepted

Comments>

Assessment of surface water exposures

Use of data from the surface water samples that included artificially elevated sediment concentrations over-estimates typical recreational exposures. Sediment was deliberately kicked prior to surface water sampling to simulate disturbed conditions, and surface water samples contained "large amounts of suspended sediment" (page 2-10). The HHRA assumes regular ingestion of 30 ml of this water a day for the warmer months of the year. Ingestion of such water may occasionally occur when young children play near the shore but would not likely occur on a regular basis and would be very unlikely for older children and adults. The HHRA, however, assumes that all ages may ingest this water regularly (up to 70 years for the traditional subsistence scenario). For developing ambient water quality criteria. EPA (1998) assumes a water ingestion rate during swimming of 30 ml/hr or 10 ml/day. One would expect that wading in muddy water would result in less gulping of water than swimming. In addition, sediment in water is less likely to cling to hands than soil would. Therefore, hand-to-mouth activity by children is not likely to result in the same intake rate as assumed for swimming.

Response>>

The HHRA assumed that adults and children using recreational areas in the Lower Basin could swallow water containing suspended sediments during the warmer months (public receptors and the special subgroup of subsistence receptors). For other areas of the Basin, adults were not assumed to be exposed to surface water, only children aged 4 to 11. For public receptors, the assumption used was that for 32 days of the year 30 ml of water was swallowed. This represents a couple of mouthfuls (about one ounce of water) that could certainly be ingested during swimming/water play activities. While it may be an overestimate we do not consider the overestimate to be unreasonable.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
315	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		1/02/2000	URS
A84		Hecla Mining and ASARCO	0-Executive Summary			Partially Accepted

Comments>

Waste pile exposures

Exposure to waste piles appears limited. The section under Upland Soil EPCs (page 3-39) notes that, in many cases, waste piles are not adjacent to residential homes (as in the case of the Nine Mile and Mullan areas) and sieved surface soil samples were not available because of lack of fines in the upper one inch due to the rocky nature of the piles. Nevertheless, the available waste pile data that could be collected are assumed to be representative of this type of exposure throughout the Basin. Given these facts, frequent visits and ingestion of large amounts of soil on waste piles (i.e., the 300 mg/day that is assumed, a value that is more than the residential RME soil ingestion rate) are not realistic assumptions. As a result, the waste pile risk calculations presented in the HHRA over-estimate the likely exposures and risks from waste piles and should be modified to reflect more realistic exposure assumptions.

Response>>

We agree that waste pile exposures are likely only an issue for elementary-aged school children where the piles are relatively close to residences and only these types of piles were evaluated in two areas of the HHRA. In addition, we agree that waste pile concentrations might be variable and these two things, location and concentration, would need to be taken into consideration for any risk management decisions regarding potential remedial actions at a waste pile. Many waste piles that are accessible on the valley floor and some of the side canyons do receive heavy use by teenagers and adults, although the pile may not be easily accessible by younger children. Therefore, many of the more remote piles do provide exposure and will be evaluated during the remedial design phase although the risk assessment did not quantitatively evaluate the older children/adult pathway. Text will be added to clarify this issue. See also response to Comment A24.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
316	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		1/03/2000	TG
A53		Hecla Mining and ASARCO	0-Executive Summary			Not Accepted

Comments>

Source identification

To understand the contributions of mining sources to elevated blood lead concentrations, blood lead statistics should ideally be recalculated excluding the data for children whose blood levels are affected by non-mining sources. For example, children with known paint exposures should be removed from the database for comparison with IEUBK model results. Because of the bias introduced by paint, which is unrelated to lead in soil from mining activities, and the inability of the model to adequately account for this source of lead separate from other sources, children and houses with known lead-based paint exposures should be removed from the database.

Response>>

The HHRA disagrees with this comment. The HHRA evaluates the potential human health risks associated with contaminated environmental media. With regard to lead, the analysis examines the effects of soil and dust lead on blood lead levels in concert with dietary and other sources. There is little indication of direct ingestion of paint particulate aside from that lead paint incorporated in soil and dust pathway. The site-specific model analysis uses observed soil and house dust lead levels. As a result, the sources of lead to dust, such as paint, yard soils, materials tracked in by workers, fugitive dusts, etc. are inherent in the analysis. The influence of lead paint on these pathways is examined by regression analysis. The interpretation of these results was that contaminated soils, house dust, and lead based paint are all related to excess absorption. Separating out the homes with known paint hazard would be difficult as most residences, other than trailer homes, have lead paint. The primary indicator of paint condition (peeling/chipping/chalking paint) has been shown in the parent 1996 Basin Exposure Study to be highly correlated with home hygiene and socio-economic status. As a result, it is not clear whether the significance of this variable is reflective of the paint source of lead, socio-economic status, personal and family behavior, home hygiene practices, or dust loading. See also General Response to Comments, #1a.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
317	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		1/03/2000	TG
A54		Hecla Mining and ASARCO	0-Executive Summary			Accepted

Comments>

Similarly, if children's exposure is thought to arise due to exposures from areas other than their own property (as noted in case follow-up records), these children should be removed from the database if comparisons are being made to IEUBK model results for residential yards.

Response>>

The HHRA agrees with this comment. A small number of children that have been identified as having exposures outside the home were included in the analysis. Appropriate discussion will be included in the final document.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
320	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		1/03/2000	TG
A85		Hecla Mining and ASARCO	0-Executive Summary			Partially Accepted

Comments>

Evaluations of potential sources should also consider that blood lead concentrations for females of reproductive age and their children may be affected by exposure from the BHSS. Blood lead concentrations and the body burden of lead of females in the Basin could be affected by past exposures to greatly elevated levels of lead in the BHSS. This body burden would also contribute to prenatal exposure to their children. Older children who have accumulated lead from past exposures in the BHSS may also have moved to the Basin. No attempt appears to have been made to account for this possible source of elevated lead exposure in the Basin.

Response>>

The HHRA agrees with this comment. Reproductive-aged female blood lead levels are greater than national norms as indicated in the HHRA. The observed geometric mean female adult blood lead level was 2.0 ug/dl and ranged from 1.6-2.6 ug/dl in the 8 geographic areas. A national default value of 1.7 ug/dl was used in the risk estimates, as the total number of samples from each area was not of sufficient size (n=12-41, see Table 6-8b) to yield statistically meaningful estimates. Similarly, national default estimates were used for estimated maternal contribution to infant blood lead levels. Use of a higher maternal contribution would result in slightly greater blood lead estimates for young children. Risk managers may want to consider risk underestimated for these individuals. Little data are available to evaluate whether the elevations noted in Basin women are due to the BHSS, Basin-wide contaminant sources, occupational exposures, or other factors.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
321	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		1/03/2000	TG
A86		Hecla Mining and ASARCO	0-Executive Summary			Not Accepted

Comments>

F. Application of the IEUBK model

As discussed above in the general comments section, the IEUBK calculations presented in the HHRA are based primarily on EPA's default exposure assumptions. Little effort is made in the HHRA to incorporate site-specific data or considerations in the modeling analyses, to refine the modeling approach to reflect site-specific information or to interpret the modeling results in light of actual observations. In particular, the HHRA modeling does not attempt to address the likely variation that exists among the identified exposure areas in factors that are likely to affect the IEUBK modeling results.

Response>>

The HHRA disagrees with this comment. Site-specific data were used for input into the IEUBK. Please see General Response to Comments, #3, #4, #8 and #9.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
322	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		1/03/2000	TG
A87		Hecla Mining and ASARCO	0-Executive Summary			Not Accepted

Comments>

In addition, in several cases, the default assumptions reflect highly conservative or outdated scientific information that also calls into question the validity of the model results.

Response>>

The HHRA disagrees with this comment. The default assumptions used in the analysis are recommended by current EPA guidance, and represent scientific consensus based on rigorous examination of national and international experience. The applicability of the various assumptions was extensively reviewed in the HHRA process and the applicability of these assumptions to the Basin and associated uncertainties are discussed in the document.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
323	10/13/2000	Hecla Mining and ASARCO	Public Draft - July 2000		1/03/2000	TG
A88		Hecla Mining and ASARCO	0-Executive Summary			Accepted

Comments>

Appropriateness of input assumptions

The various input assumptions and data used in the model runs should be more clearly presented in the report. Even if many default assumptions are used, these should be listed in a summary table. As presented, the assumptions used for the various model runs are difficult to reconstruct. Specific comments on input assumptions are discussed below.

Response>>

The HHRA agrees with this comment. All the assumptions are included in various Tables throughout the document. A summary table will be added to the final document to consolidate the presentation.

Misc. Input>>

Local Governments

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
212 **B1**	10/03/2000	R. Merril Coomes Local Governments	Public Draft - July 2000 0-Executive Summary		0/31/2000	URS Not Accepted

Comments>

Conceptual Site Models (CSMs) appear to be based on ecological concerns and not human health issues.

Response>>

The fate and transport of mining materials does not differ between ecological and human receptors. The applicable human receptor pathways are included on the CSM figures in Section 3.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
213 **B2**	10/03/2000	R. Merril Coomes Local Governments	Public Draft - July 2000 0-Executive Summary		0/31/2000	URS Partially Accepted

Comments>

The CSMs in the Report are very different than in Field Sampling and Analysis Plan (FSAP) Addendum 05, which was used to plan data collection.

Response>>

The CSMs in the HHRA contain much more detail regarding release mechanisms and also included other receptor groups than just "recreational." The CSM in FSP05 focused only on recreational receptors and contained no detail under "mechanisms." While FSP05 listed several different types of recreational activities that could be practiced partly because both lower and upper basin areas were sampled, the HHRA did not quantify all possible recreational activities, but selected exposure parameters protective of all recreational activities within a given geographical region and only quantified one risk for recreational activities per receptor group per area. For example, only one risk/hazard for each COPC was calculated for public recreational risks in the Lower Basin. The risk/hazard estimate reflects all types of recreational activities by the public in this area assuming equal exposure time to the different media and that any of the individual recreational areas are as likely to be used as any other. Therefore, only one recreational receptor "box" was included for each of the HHRA area-specific CSMs. Text will be added to clarify this issue.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
214 **B3**	10/03/2000	R. Merril Coomes Local Governments	Public Draft - July 2000 0-Executive Summary		0/31/2000	URS Not Accepted

Comments>

It is not clear that data collection meets the needs for the CSMs in the Report.

Response>>

The human exposure routes identified on the CSMs and quantitatively evaluated in the report had sufficient data to calculate risks. In a few cases data that was collected for ecological concerns was used in the report and the implications of using it were discussed in Section 7 of the HHRA.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
215	10/03/2000	R. Merril Coomes	Public Draft - July 2000		0/31/2000	URS
B4		Local Governments	0-Executive Summary			Partially Accepted

Comments>

Data from upland soil, collected at a depth of 0 to 1-inch and sediment collected at 0 to 6-inch and 0 to 12-inch depths were combined in the Report to evaluate potential risk to one receptor, a 4 to 11 year-old child. The data were collected to estimate exposure to campers (0 to 1-inch) and swimming and wading children (sediment). These data were collected for different uses and were not intended to be combined. A statistical analysis of the Blackwell Island data (the only area for which sufficient data exists to make the analysis) shows that the data cannot be combined (they are independent data sets and do not have sufficient statistical similarities to justify combining. Combining these data sets is similar to combining the weights of apples and oranges, there are too many differences to make the results meaningful. The review identified many similar data management situations.

Response>>

We acknowledge that upland soil and beach sediment data may be statistically different for some chemicals for some sites. However, while this may be an important issue for nature and extent issues, any differences that may exist in sample means is not relevant in this HHRA because of the exposure assumptions used in calculating risk. Therefore, the soil and sediment data were appropriately combined for the Lower Basin neighborhood and public receptors for the following reasons: 1) The "upland" areas and the "beach" areas of the Lower Basin are in close proximity to one another. 2) The "upland" areas have all been impacted by previous flood events and therefore experienced a mixing of soil and sediment materials. For this reason, this material was identified as "floodplain soil /sediment" and refers to materials within the approximately 1-mile wide flood plain area. 3) Lastly, a receptor is presumed to spend an equal amount of time in upland areas as in beach areas. It is also assumed that receptors will have an equal probability of visiting one CUA in the Lower Basin as another. Therefore, the data was appropriately combined for the Lower Basin neighborhood and public receptors and an average concentration across the entire Lower Basin is an appropriate use of the data.

See Appendix E where the details including sample number, depth, and media, are provided for all recreational data (except Blackwell Island which was inadvertently not included--it will be added), and Appendix F which contains all data used in the calculations.

With respect to Blackwell Island, however, we acknowledge that soil and sediment data are not statistically the same and because Blackwell Island's upland and beach areas are spatially separated (unlike in the Lower Basin), the assumption of equal time spent between the upland and beach areas may not be as valid in this instance. Therefore, separate risk evaluations may have been more appropriate. An evaluation of this data shows that the higher sediment concentrations are driving the risks and hazards for Blackwell Island. This will be taken into consideration during risk management decisions.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
216	10/03/2000	R. Merril Coomes	Public Draft - July 2000		0/31/2000	URS
B5		Local Governments	0-Executive Summary			Not Accepted

Comments>

Evaluation of soil/sediment data for the Lower Basin identified significant variability over the entire Lower Basin and within small areas of the Lower Basin. It is not appropriate to evaluate a large area (make risk-based decisions) when there is highly variable data from even small portions of the entire area.

Response>>

The risk estimates for Lower Basin use assume any of the Lower Basin areas are as likely to be used as any other; therefore, combining the data is appropriate. Risk management decisions regarding Lower Basin remediation will be made on a site-by-site basis (i.e., by common use area, not for the entire Lower Basin as a whole) as described in the Technical Memorandum for Human Health Alternatives. Risk management decisions for non-lead chemicals are not addressed in the document. See also response to Comment B4.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
217	10/03/2000	R. Merril Coomes	Public Draft - July 2000		0/31/2000	URS
B6		Local Governments	0-Executive Summary			Not Accepted

Comments>

When a screening-level risk assessment suggests a potential risk, for example Blackwell Island, EPA guidance states that exposure point concentrations and exposure parameters should be modified for the Baseline Risk Assessment. The modifications may include additional data collection or modifying exposure parameters to be more representative of actual land use. Exposure parameters in the Baseline Risk Assessment are identical to those in the Screening Level Risk Assessment and additional data have not been collected for Blackwell Island or Harrison Beach. Although Harrison Beach was identified for further evaluation, it is not evaluated in the Report. The assumption that the quantity and quality of data collected for Screening Level Risk Assessment is appropriate for Baseline Risk Assessment requires discussion in the Report. The acceptable uncertainties in screening level evaluations are much greater than those for a Baseline Risk Assessment.

Response>>

Sites in the screening level risk assessments were screened using a hazard quotient of 0.1 rather than 1 which added a level of protectiveness to the screening level document that is not incorporated into the baseline risk assessment. After review by the HHRA stakeholder team, it was decided that the exposure assumptions regarding frequency of site use used in the screening-level document were appropriate for the RME exposure scenario in the baseline RA for Blackwell Island. In addition to the RME scenario, a CT scenario was added in the Baseline RA.

Harrison Beach was evaluated in the Baseline RA as part of the Lower Basin and is first specifically noted as included in Section 2.1.3. Also the title of the HHRA is "...from Harrison to Mullan..."

Over 400 samples of floodplain soil and sediment were collected from 33 Lower Basin recreational areas using a randomized sampling scheme within each area (approximately 15-20 miles of river). This quantity of data is considered sufficient to evaluate recreational use in this area. Data quality (laboratory analysis) met all requirements for Baseline RA's.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
218	10/03/2000	R. Merril Coomes	Public Draft - July 2000		0/31/2000	URS
B7		Local Governments	0-Executive Summary			Not Accepted

Comments>

Evaluating the child-only exposure scenario to determine noncarcinogenic risk is “overly conservative”, based on EPA’s Science Advisory Board’s (SAB) evaluation. SAB indicates that an adult/child scenario is sufficiently conservative and is recommended to determine hazard quotients.

Response>>

We disagree with this comment. The White House issued a policy statement on April 27th, 1997 regarding health risks to children which states "It is the policy of the USEPA to consider the risks to infants and children consistently and explicitly as part of risk assessments...the Agency will develop a separate assessment of risks to infants and children...".

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
219	10/03/2000	R. Merril Coomes	Public Draft - July 2000		0/31/2000	URS
B8		Local Governments	0-Executive Summary			Not Accepted

Comments>

Statistical approaches used to determine the number of samples required to estimate exposure point concentrations are different in the Report and the Field Sampling and Analysis Plan (FSAP). The FSAP indicated that seven samples were adequate to support human health risk assessment, but the Report states that ten samples are required. This is confusing, because the FSAP was designed to collect samples to support risk assessment. An explanation is required in the Report.

Response>>

An explanation of the reasons for 7 versus 10 samples is provided in Section 3.3.1, in the last paragraph on page 3-35.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
220	10/03/2000	R. Merril Coomes	Public Draft - July 2000		0/31/2000	TG
B9		Local Governments	0-Executive Summary			Not Accepted

Comments>

The report calculates correlation coefficients to a high confidence level and concludes that the variables are “significantly correlated”. Few correlation coefficients were greater than 0.5. Actually, correlation coefficients below 0.5 are poor indicators of data predictability (predicting or explaining one value in terms of the other is the goal of correlation coefficients). A correlation coefficient less than 0.5 means that at least fifty percent of the variability in the data cannot be accounted for in the analysis. This is not a “significant” correlation.

Response>>

The HHRA disagrees with this comment. Correlations that were considered significant were based on that correlation's p-value. A correlation was considered significant if the p-value was 0.05 or less. There is also confusion as to the difference between an r and an R-squared. R-squared values used for regression analyses explain variation in the dependent variable, not an r. Numerous articles from scientific journals on environmental epidemiology of environmental contaminants explain that there is no "magic number" which an association has to reach or exceed in order to offer interpretive value. Secondly, it is not the case that a "coefficient" less than 0.5 is not indicative of a "significant" association. Whether some value is or is not hinges not only on the level of statistical significance but also on the particular statistical design or statistical model being used. In the typical practice in epidemiological studies with complex biostatistical components, even very good associations in population studies can be less than "0.5", especially if the particular association being tested has been over-controlled for confounders that subsume within their controlling an environmental lead component. Please see General Response to Comments, #3d.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
221	10/03/2000	R. Merril Coomes	Public Draft - July 2000		0/31/2000	URS
B10		Local Governments	0-Executive Summary			Partially Accepted

Comments>

There are 83 and 74 matched data sets for soil, floor mats, and house dust, but it is stated there are insufficient data to statistically analyze. This is difficult to understand, based on the characteristics of statistical test parameters. The Report should provide the analysis and identify the potential correlation for the data sets, similar to that done in Section 6.4.1.

Response>>

The text states that there is insufficient data for each geographic subregion for statistical analysis and that there is not paired soil-dust data for every home for the non-lead metals. For six of the eight geographical areas, less than 10 house dust samples were available, too few for statistical analysis given the large variability of concentrations in dust (explained on page 3-38 and in detail on page 7-14). The primary reason the data were not used in the risk and hazard calculations was because of the uncertainty of the relationship between soil and dust, making a quantitative prediction of dust concentrations where we did not have data highly uncertain. The uncertainty in predicting dust concentrations from soil concentrations was considered more problematic than just using the soil data. In addition, while the soil-dust relationships for lead are reasonably well characterized, the soil-dust relationship for non lead contaminants is not. The majority of risk assessments to date do not have indoor dust concentrations for chemicals other than lead, thus using the soil data as a surrogate has precedence throughout the country. Paired soil and dust data for lead were available for every home, so the lead risk assessment did not have to predict a relationship in the absence of data. Additional text will be added to Section 3 to clarify these issues.

The assumptions and reasons for not using the house dust data are discussed on pages 3-38 to 3-39 and further discussed in Section 7, page 7-14, table 7-1. Statistical correlations are provided in Appendix I.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
222	10/03/2000	R. Merril Coomes	Public Draft - July 2000		0/31/2000	URS
B11		Local Governments	0-Executive Summary			Partially Accepted

Comments>

The sampling strategy used to collect waste pile samples does not appear to be appropriate to support risk assessment, based on EPA guidance. The samples appear to be from a biased or judgmental sampling strategy and were collected to characterize the waste piles. They do not appear to have been collected to estimate potential exposure (random sampling).

Response>>

The sampling strategy was appropriate per page 6-28 of EPA, 1989 RAGS Part A: "In some cases, contamination may be unevenly distributed across a site, resulting in hot spots (areas of high contamination relative to other areas of the site). If a hot spot is located near an area which, because of site or population characteristics, is visited or used more frequently, exposure to the hot spot should be addressed separately."

Waste piles close to residential homes were sampled along Canyon and Ninemile Creeks and in Mullan specifically to estimate exposure. Children were observed playing on these piles or were reported as having played on them; therefore, piles were sampled "purposively". Discussion will be added to Section 2 to clarify waste pile sampling and use.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
223	10/03/2000	R. Merril Coomes	Public Draft - July 2000		0/31/2000	URS
B12		Local Governments	0-Executive Summary			Not Accepted

Comments>

In addition, it is stated that the 0 to 1 inch depth was not be sampled because sufficient fine material was not present at this depth. However, the fine material in the 0 to 1-inch depth interval is important for risk assessment, because children are exposed to this interval.

Response>>

Fine material is present in the top inch and this material would stick to children's hands and be ingested; however an insufficient amount was present for laboratory analysis. The assumption is that the concentration found in the 0-6 inch depth is representative of the concentration in the top inch.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
224	10/03/2000	R. Merril Coomes	Public Draft - July 2000		0/31/2000	URS
B13		Local Governments	0-Executive Summary			Not Accepted

Comments>

Exposure areas are not physically defined. For example, a residential yard is generally assumed to be ¼ acre. The Report infers that the Lower Basin risk levels apply to the entire Lower Basin area. The estimated risk actually applies to the small individual areas adjacent to the Coeur d'Alene River that were sampled or to the four residences that were sampled. When the exposure area is not defined, it is difficult to identify 1) the area that requires remedial action and 2) whether sufficient data were collected to support the decision. Defining exposure area is a critical part of data collection and risk assessment, but the Report does not perform this important task.

Response>>

The CdA Basin is large and complex and it is neither possible nor necessary to sample all of it. We acknowledge that human exposures would only occur in a portion of the large "exposure areas" identified on the maps in Sectoion 3. The RA identified certain activities that could be "risky" depending on actual concentrations and frequency of use, e.g., recreational activities in the Lower Basin. Remedial actions will be made on a home-by-home basis and will not occur without sampling (if there is no data). Common use area remedial activities would be determined on a site-by-site basis. It is highly unlikely that any remedies will be applied wholesale to large areas where variable concentrations and human use patterns exist.
Data from 13 residences are included in the non-lead EPC values for the Lower Basin, not 4, see Table 3-21.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
225	10/03/2000	R. Merril Coomes	Public Draft - July 2000		0/31/2000	URS
B14		Local Governments	0-Executive Summary			Partially Accepted

Comments>

The exposure area for a construction worker in the Lower Basin is much greater than a few feet from the bank of the ten-mile stretch of the Coeur d'Alene River that was characterized in the Lower Basin. The assumption that this small area represents the construction worker exposure area may result in over estimated risk and inappropriate risk-management decisions (is active remediation required to protect construction worker health?). It is recommended that exposure areas are defined for all receptors in all locations evaluated for the risk assessment.

Response>>

We acknowledge that risks to construction workers in the Lower Basin are likely over-estimated. If a construction worker is disturbing flood plain soil/sediment in the Lower Basin, then some potential for adverse health effects may be possible and the communities need to be aware of this. In reality, if there is a possibility that a construction project will disturb soils and sediments that have been impacted by mining, then samples should be collected and steps taken to protect the worker. This scenario is already part of the Institutional Control Program in the Upper Basin. The HHRA identifies that mining-contaminated soils could be a problem for construction workers but due to the large area of the Basin every "safe" or "unsafe" area cannot be explicitly identified by the HHRA.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
226	10/03/2000	R. Merril Coomes	Public Draft - July 2000		0/31/2000	URS
B15		Local Governments	0-Executive Summary			Accepted

Comments>

Dermal exposure for children (no shoes, shorts, short-sleeved shirts) from April through November does not agree with local climatic conditions. The number of months for this exposure frequency needs to be reduced to reflect reality. Assuming children are bare foot April through November in the Coeur d'Alene Basin is not likely to pass a "smile test" and leads to public questioning of the "professional judgement" used in the risk assessment.

Response>>

We agree that the dermal surface areas used for the 4 to 11 year old age group were too large for the exposure period. Text and a table will be added to the report which demonstrate how calculated risks and hazards will be affected by alterations in surface area. Preliminary estimates indicate neighborhood exposure estimates will drop by <10%. Risks and hazards for combined neighborhood exposures do not drive the overall risks and dermal exposures were a relatively low percentage of the total neighborhood risks in the report (35% to 17% for arsenic). Hazard indices only slightly exceeded 1 for neighborhood receptors for two areas: Side Gulches (which was based on Elk Creek Pond, since remediated), and Burke/Ninemile (which included waste piles). Therefore, changing skin surface areas for neighborhood exposures will not affect the conclusions of the risk assessment or potential risk management strategies.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
227	10/03/2000	R. Merril Coomes	Public Draft - July 2000		0/31/2000	URS
B16		Local Governments	0-Executive Summary			Not Accepted

Comments>

The Report does not include the analytical data in a way that allows relationships between contaminants and exposure areas to be reviewed. For example, the exposure point concentrations are very different for construction workers, recreational children, and residents. Where are these exposure areas? They should be defined on maps that identify sampling locations. Because this information is not included, the exposure point concentrations and estimated risk cannot be confirmed by the public.

Response>>

The details of the analytical data used to calculate the recreational EPCs (except Blackwell Island which will be included) are presented in Appendix E. The 15 maps in Section 3 show the approximate sample locations for all data except residential. Some of the common use areas have sample numbers combined by area in the interests of consolidating the map requirements. Appendix F presents all of the data used to quantify risks by exposure area and it also includes the residential data and Blackwell Island. Section 3, pages 3-38 to 3-41 describes the data used to calculate each EPC. Appendix A contains every input to every risk calculation with formulas.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
228	10/03/2000	R. Merril Coomes	Public Draft - July 2000		0/31/2000	URS
B17		Local Governments	0-Executive Summary			Not Accepted

Comments>

The detection limits for non-detects and analytes that were not analyzed are not reported.

Response>>

The mining-related chemicals have been correctly identified and agree with historical assessments. Detection limits for other chemicals, not mining-related, would not affect the risk assessment. In addition, detection limits are reported in the Field Sampling Plans.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
229 **B18**	10/03/2000	R. Merril Coomes Local Governments	Public Draft - July 2000 0-Executive Summary		0/31/2000	URS Partially Accepted

Comments>

Note that the Lower Basin had only four sample locations and 25 to 28 individual analyses to estimate the exposure point concentration. It is not clear that the quantity of data is sufficient to support decision-making over such a large area.

Response>>

There were 13 homes sampled in the Lower Basin for non-lead. See Table 3-21. Therefore, thirteen locations with a total of 28 samples were used in the calculations. Risk management decisions will not be made for the entire area, they will be made on a house-by-house basis and never in the absence of location-specific data.
The summary table in Appendix E included only EPA data, not the additional residential data from the State used in the non-lead EPCs. We will delete any reference to residential data from the Appendix E Table. All residential data is included in Appendix F by geographical area.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
230 **B19**	10/03/2000	R. Merril Coomes Local Governments	Public Draft - July 2000 0-Executive Summary		0/31/2000	URS Not Accepted

Comments>

Analytical data are not identified by sample number in the report. Only statistical summaries are provided (they list individual analytical results) and the summaries often combine different media (upland soil and sediment of various depths). The actual data for metals other than lead should be provided by sample number and depth.

Response>>

Appendix E lists all the data used to calculate EPCs (except the residential EPCs and Blackwell Island) by media. The sample number and depth (where applicable) are both identified in these tables. Appendix F contains this same data as well as the residential data.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
231 **B20**	10/03/2000	R. Merril Coomes Local Governments	Public Draft - July 2000 0-Executive Summary		0/31/2000	URS Partially Accepted

Comments>

There are inconsistencies between exposure frequency for incidental soil ingestion and dermal contact for residential, neighborhood recreational, and public recreational receptors. These exposure frequencies must be identical for a given receptor. For example, the public recreational receptor cannot be exposed to soil by skin contact for 68 days and incidentally ingest soil for 30 days. Incidental soil ingestion is due to hand-to-mouth transfer of soil and any time there is skin exposure; there is incidental ingestion. This inconsistency requires correction for several receptor populations evaluated in the risk assessment.

Response>>

The exposure frequencies for dermal absorption and ingestion are the same. The units for dermal exposure, however, are "hours per event" while the units for ingestion are "hours per day". The ingestion exposure frequency was normalized to 14-waking-hour days. This is explained in the table notes for Tables 3-23 and 3-24. However, a discussion will be added to the report to clarify this point and a table will be added to show more explicitly the steps that were taken to arrive at the exposure frequencies.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
232 **B21**	10/03/2000	R. Merril Coomes Local Governments	Public Draft - July 2000 0-Executive Summary		0/31/2000	URS Accepted

Comments>

The Report should clearly state the differences between EPA's "acceptable cancer risk range" and the level of risk that warrants remedial action. The 1.0E-4 to 1.0E-6 range (a range of one additional cancer in 10,000 exposed individuals to one additional cancer in 1,000,000 exposed individuals) is a Superfund cleanup goal for sites that undergo remedial action. A 1.0E-04 cancer (one in 10,000 exposed individuals) risk is the level at which remedial action may be warranted, assuming no other adverse environmental impacts.

Response>>

Discussion will be added to the report which notes these differences. We also note that risks over 10-4 are not the only time action is warranted. The NCP allows actions at lower risk levels depending on site-specific conditions.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
233 **B22**	10/03/2000	R. Merril Coomes Local Governments	Public Draft - July 2000 0-Executive Summary		0/31/2000	TG Not Accepted

Comments>

Based on EPA guidance, EPA's Integrated Exposure Uptake Biokinetic (IEUBK) Model, which is used to predict child blood lead levels, is not appropriate to evaluate periodic or episodic exposure to lead. However, the Report evaluates periodic lead exposure with the IEUBK Model. Because the Report "force fits" an episodic or intermittent exposure scenario into the IEUBK Model, there is disagreement with EPA guidance and the basis of the Model.

Response>>

The HHRA disagrees with this comment. The IEUBK model is relevant for continuous exposures that are of sufficient duration to produce quasi-state blood lead concentrations. The incremental exposures evaluated by IEUBK analysis should not be characterized as episodic. The exposures evaluated are seasonal in nature, occurring over 6 to 8 month periods, with event frequencies of at least once per week. The TRW comments at Section 2.5 provide additional discussion regarding this topic. See also General Response to Comments, #5a, #5b, and #9a.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
234 **B23**	10/03/2000	R. Merril Coomes Local Governments	Public Draft - July 2000 0-Executive Summary		0/31/2000	TG Not Accepted

Comments>

The exposure assumptions used in the IEUBK Model for the Upland Parks and Schools recreational receptors assume an exposure frequency of 238, rather than 68 days per year (twice a week for 34 weeks). This overestimates the potential lead intake and blood lead levels by a factor of 238/68 (three and one-half times). A similar overestimate of exposure frequency is made for other receptors and exposure scenarios that occur away from the yard.

Response>>

The HHRA disagrees with this comment as it is inconsistent with the methodology employed in the HHRA. The Central Tendency (CT) Exposure Frequency is a 7 hour/day event, one-day per week, for 34 weeks. The RME factor is the same for two-days per week. The total number of hours spent on the recreational activities by children at Upland Parks are equivalent to 17 and 34 days, respectively, adjusted for waking hours. The RME exposure does occur on 68 days over a 238 day season. The HHRA averaged the 17 days of equivalent exposure over 365 days for inclusion in IEUBK model. The TRW comments on Section 2.5 provide additional discussion regarding this topic. The TRW concludes that the exposure duration is sufficient to include in IEUBK analysis, but believes the risk may be understated, by about 35%, as the exposure should be averaged over 238 days, rather than 365 days. See also General Response to Comments, #5a and #5b.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
235	10/03/2000	R. Merril Coomes	Public Draft - July 2000		0/31/2000	URS
B24		Local Governments	0-Executive Summary			Partially Accepted

Comments>

The Data Evaluation Section of the Report simply reviews the laboratory data quality and does not demonstrate that: the data are appropriate for risk assessment. The report does not compare the collected data with criteria identified in EPA's Data Usability in Risk Assessment Guidance (EPA 1992).

Response>>

While not explicitly noted in the text, the four data application issues from the 1992 guidance were met and are as follows:
1. What contamination is present at what levels? -- Adequately addressed in Section 2 which describes sample collection methods, data analysis procedures (metals), and notes where samples were collected specifically for human health needs versus other uses. The vast majority of the data used in the HHRA was collected based on human health considerations and fulfills the requirements of risk assessment guidance described in EPA's 1989 Risk Assessment Guidance for Superfund and in the 1992 document. For the relatively small amount of data used that was not collected for HHRA use (sediment and surface water data in the South Fork, Canyon Creek, and Ninemile Creek), the uncertainties surrounding this data are discussed in both Section 2 and in Section 7 of the report. Other than the data noted above and the special case of waste piles, all samples were collected using a randomized or systematic sample design appropriate for risk assessment evaluations.
2. Are site concentrations different from background? -- Adequately addressed in Section 2 which presented background concentrations for applicable media (except groundwater) and selected COPCs based on concentrations exceeding background levels and health levels.
3. Are all exposure pathways identified and examined? -- Adequately addressed in Section 3 where exposure pathways were exhaustively discussed and conceptual site models by human health geographic area were presented.
4. Are all exposure areas fully characterized? – Human health exposure areas were discussed in Section 3. However, they were not explicitly defined in many cases due to the large and complex area of the Basin. This lack will be addressed in documents addressing remediation which will select individual locations on an area-by-area basis. See previous response to Comments B5, B13, B14 on exact exposure area definitions versus risk management practices.

Text will be added which briefly discusses the data usability guidance and the existing discussions mentioned above will be identified as fulfilling the appropriate data application issue from the 1992 guidance.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
236	10/03/2000	R. Merril Coomes	Public Draft - July 2000		0/31/2000	URS
B25		Local Governments	0-Executive Summary			Partially Accepted

Comments>

The Data Evaluation Section of the Report simply reviews the laboratory data quality and does not demonstrate that: the Data Quality Objectives used to plan data collection, were met (DQO Process guidance, EPA 1993). The Report should compare the quantity and quality of the collected data with that planned in the Field Sampling and Analysis Plan (FSAP) to ensure that collected data support making decisions identified in the FSAP at the specified confidence levels, and

Response>>

See General Response to Comments regarding DQO/DQA issues and responses to Comments B3 and B6. In general, the data that was collected for use in the HHRA was of the same quality and quantity and at the specified confidence levels (either 95 or 99 percent) as that planned in the FSPAs. We note that FSPAs 6,7, and 12 were residential samplings and sampled only on a volunteer basis. The risk assessment discusses the limitations of using volunteer data in the uncertainty section. However, for the lead risk assessment over 800 homes in the basin were sampled. Leading the human health risk assessment team to believe that this data set is sufficient to adequately evaluate risks. As discussed in the General Response to the DQO comments, the DQO process was considered and documented to varying degrees in each of the FSPAs. Therefore, for further discussion see the specific FSPAs and their alterations reports. Text will be added to Section 2.3 which briefly discusses the DQO process and how it was followed and a reference for Section 4.2 of Part 1 of the RI will be added which refers the reader to further discussion on the DQO process.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
237	10/03/2000	R. Merril Coomes	Public Draft - July 2000		0/31/2000	URS
B26		Local Governments	0-Executive Summary			Partially Accepted

Comments>

The Data Evaluation Section of the Report simply reviews the laboratory data quality and does not demonstrate that: the data are of the quality identified as needed to support decisions that were identified. This data quality analysis would follow EPA's DQA Guidance (EPA 1998).

Response>>

See General Response to DQO comments and responses to Comments B3, B24, and B25. We are unclear what decisions the reviewer is referring to. The purpose of the Risk Assessment is to quantitatively evaluate risks and to provide qualitative discussions of the uncertainties associated with use of the available data. We believe that the data used in this risk assessment adequately supports the risk conclusions that were made. Text will be added to Section 2.3 which briefly discusses the DQA process and how it was followed and a reference for Section 4.2 of Part 1 of the RI will be added which refers the reader to further discussion on the DQA process.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
238 **B27**	10/03/2000	R. Merril Coomes Local Governments	Public Draft - July 2000 0-Executive Summary		0/31/2000	TG Not Accepted

Comments>

The Report identifies good agreement between measured and modeled blood lead values. This leads the public to believe that the model predictions are appropriate to protect their children from over exposure to lead. Unfortunately, the comparison made in the Report is simply comparing the two data sets (measured and modeled blood lead levels) a technique that does not support a conclusion that the model is accurately predicting blood lead. Causality between modeled and measured values is assumed and not supported. A "nonsense" example of a "spurious correlation" that is a statistical fact is this: "There is a close relationship between the salaries of Presbyterian ministers in Massachusetts and the price of rum in Havana." Which is the cause and which the effect? In other words, are the ministers benefiting from the rum trade or supporting it? [Taken from "How to lie with Statistics, D. Huff, 1954]. Agreement between modeled and measured blood lead levels must be evaluated for individuals that have measured blood lead levels and yards that have been characterized. The Report indicates that individuals were modeled in the batch mode, which means all data are entered to predict each individual's blood lead, based on the analytical data for the individual's environment. These individual predictions can be compared to the measured blood lead values as paired data. If the model accurately predicts the blood lead, a scatter plot of modeled versus measured data will show a high correlation coefficient and most of the predicted high blood levels will correlate with high measured levels. The scatter plot will identify the number of children at risk (blood lead greater than 10 ug/dl) that are not identified by the IEUBK Model and the number of children predicted by the Model to exceed 10 ug/dl that actually do not. This information will help the public and the risk manager to understand the uncertainty in IEUBK Model results in terms of protecting children's health. If there is a significant difference between the individual measured and Modeled blood lead levels, it is recommended that the issue be reviewed by EPA's Lead Technical Review Workgroup, as suggested by EPA guidance.

Response>>

The HHRA disagrees with this comment. The relationship between blood lead levels and environmental exposures is examined throughout the HHRA by a variety of methods. In regression analysis, it is common practice to compare dependent blood lead levels predicted from independent exposure variables to observed concentrations. In the IEUBK analysis, the same independent exposure variables are input to a mechanistic model and outcome blood lead levels are predicted. It is also common to compare these predictions to observed blood lead levels. Both the dependent and independent variables come from the same home and community and the objective of the analysis is to investigate and quantify any relationship between the variables. The regression analysis discussed above shows a relatively strong relationship, that is consistent with plausible environmental and biological processes, and is similar to the findings of investigations at other sites including the BHSS. As a result, it is appropriate to compare predicted and observed blood lead levels in both empirical and mechanistic procedures. The HHRA has been extensively reviewed by the EPAs Technical Review Workgroup (TRW) for Lead and the review is attached.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
239 **B28**	10/03/2000	R. Merril Coomes Local Governments	Public Draft - July 2000 2-Section 2		0/31/2000	URS Not Accepted

Comments>

Conceptual Site Models (CSMs) appear to be based on the ecological risk assessment needs and concepts. CSMs are not geographical areas as defined in Section 2. The CSM graphic and supporting text simply defined (based on existing knowledge) how chemicals are transported from a source to a locations where receptors are exposed. The CSM identifies the sources being investigated, the release mechanisms of chemicals from identified sources, the transport mechanism of released chemicals from the source to the exposure point, and the intake routes of media containing transported chemicals at exposure points. The CSMs in the Report do not focus identifying the problem and data needs for human health risk assessment. The Data Quality Objectives Process Guidance (EPA 1993) indicates that identifying the problem is fundamental to determining the data needs and the decisions that are to be supported by those data.

Response>>

The fate and transport of mining materials does not differ between ecological and human receptors. The applicable human receptor pathways are included and the data exists to support evaluation of the quantified pathways. Section 2 defines CSM Units which are geographical areas that were defined for RI/FS purposes. The purpose of this section was to link the study areas of the HHRA and the EcoRA. Section 3.2.1 describes the CSM diagrams (Figures 3-3 to 3-11) and how they are applied in selecting media and pathways of concern to human health. See also response to Comment A26.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
240 **B29**	10/03/2000	R. Merril Coomes Local Governments	Public Draft - July 2000 2-Section 2		0/31/2000	URS Partially Accepted

Comments>

The amount of time that 4-11 year-olds are assumed to be outdoors playing in various recreational activities, 10 hours on beach areas and 7 hours twice a week for upland soil exposure does not appear to be supported by EPA's Exposure Factors Handbook (EFH). Tables 14-1 through 14-9, of the EFH list mean and median exposure times outdoors, and for total recreation do not appear to support the exposure times listed in the Report. Documentation that is more specific is suggested. Because the exposure assumptions are over relative long periods of time (ranging from 16 to 34 weeks), it is assumed the exposure is chronic in nature. For a chronic outdoor exposure time EPA estimates the average 3-11 year-old child spends less than 4.7 hours each day (Table 14-12, Exposure Factors Handbook). This value is significantly lower than the exposure times given in the Report, which appear to be undocumented professional judgement. Professional judgement requires documentation or support for these rather significant differences from EPA's guidance.

Response>>

Chapter 14 in the 1997 EFH is the breast milk chapter, not the activity factors chapter; therefore, we were not able to refer to the tables listed in this comment. However, the exposure frequencies used for the 4-11 year old age group are values from the 1997 EPA Exposure Factors Handbook, Chapter 15. This document is cited as the source of the exposure frequencies. Specifically, information from tables 15-104, 15-108, 15-110, 15-132, 15-135, and 15-176 were reviewed and used to select RME values. A value of 10 hours per day was not used for neighborhood exposures, but only public exposures which assumed people would be traveling some distance to get to the recreational area and would spend the entire day there. Neighborhood exposure times were either 7 hours per day (EFH Table 15-176 recommended weekend time) or 3 hours per day (EFH Table 15-132 50th percentile time for 5-11 yr olds, rounded up from 2 and 1/2 hours to 3 hours, also consistent with assumptions made for the Bunker Hill Superfund site RA).

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
241 **B30**	10/03/2000	R. Merril Coomes Local Governments	Public Draft - July 2000 2-Section 2		0/31/2000	URS Not Accepted

Comments>

Blackwell Island is to be developed into a recreational area through the efforts of the county, state agencies, and the public. This is written on a sign at the entrance (north of highway) to the area. There is a "no swimming" sign, apparently to warn of unacceptable metal concentrations on the south side of the highway. However, there is little or no evidence that receptors are frequenting the area on the south side of the highway. Figure 1 is a photo of the area does not show evidence of recent use.

Response>>

The risk assessment covers future as well as current use assuming no remediation efforts are made (baseline conditions). No evidence of current use does not mean there will be no use in the future, particularly as Blackwell Island is an identified recreational area.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
242 **B31**	10/03/2000	R. Merril Coomes Local Governments	Public Draft - July 2000 2-Section 2		0/31/2000	URS Not Accepted

Comments>

The trail on the north side of the highway leads to the water. Figure 2 is an overview of the area north of the highway and documents the lack of significant "beach" areas. There is a small area of course sand or fine gravel approximately 15 feet long and 4 feet wide along the river's edge, which is shown in Figure 3. All other areas have vegetation growing to the water's edge as shown in Figure 2. It is not clear from the Report whether sample locations represent the recreational receptor exposure area.

Response>>

Areas to be sampled were selected by local individuals familiar with the recreational use patterns of the area. Sample locations can be found in Appendix B, Figures B-17A and B-17B. See also response to Comment B30.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
243 **B32**	10/03/2000	R. Merril Coomes Local Governments	Public Draft - July 2000 2-Section 2		0/31/2000	URS Not Accepted

Comments>

Sampling locations should be identified for Blackwell Island. Recreational activities observed in the early morning included a jogger and a fisherman at the channel that causes Blackwell Island to be an island. It is recommended that the receptor populations hypothesized for Blackwell Island are reevaluated and supportive rationale provided for the selection.

Response>>

The intent of the HHRA is to provide risk estimates under reasonable maximum exposure scenarios. We acknowledge that "reasonable maximum" likely overestimates site use for many individuals; however, the overestimate is consistent with EPA risk assessment policy which makes health protective assumptions to protect public health. See response to Comment B4 and B30. Sample locations can be found in Appendix B, Figures B-17A and B-17B.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
244 **B33**	10/03/2000	R. Merril Coomes Local Governments	Public Draft - July 2000 2-Section 2		0/31/2000	URS Partially Accepted

Comments>

The relationship between the identified exposure area and the sample locations should be described in the Report. FSAP 05 indicated that photos were taken of the area sampled and that the beach area was estimated in the field by pacing or stepping the area. This information should be included in the Report. Based on field observations, it appears that the risk evaluation and any remedial action would be limited to the small 15 by 4-foot area.

Response>>

See response to Comment B4 and B30.
Discussion will be added to the report to clarify the Blackwell Island beach area and a citation will be added to refer the reader to the photo in Appendix B, page A-5 and the diagrams in Appendix B, Figure B-17A and B-17B.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
245 **B34**	10/03/2000	R. Merril Coomes Local Governments	Public Draft - July 2000 2-Section 2		0/31/2000	URS Not Accepted

Comments>

Future development by the county, state, and the public will dramatically change the existing metal concentrations. This should be considered in evaluating future potential risk.

Response>>

See response to Comment B30.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
246 **B35**	10/03/2000	R. Merril Coomes Local Governments	Public Draft - July 2000 2-Section 2		0/31/2000	URS Not Accepted

Comments>

EPA's risk assessment guidance (EPA 1989, page 25) states "if a screening level approach suggests a potential health concern, the estimates of exposure should be modified to reflect more probable exposure conditions." It is not clear how the exposure estimate was modified for the Baseline Risk Assessment, compared to the expedited screening level risk assessment for Coeur d'Alene beach areas. The differences should be identified.

Response>>

See response to Comment B6.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
247 **B36**	10/03/2000	R. Merril Coomes Local Governments	Public Draft - July 2000 3-Section 3		0/31/2000	URS Not Accepted

Comments>

Evaluating a child-only exposure scenario for non-carcinogenic health effects is overly protective (EPA's Science Advisory Board, 1993). SAB concluded that evaluating child exposure in combination with chronic toxicity criteria is overly protective. However, they noted that the approach may be appropriate for chemicals with chronic reference doses (RfDs) based on health effects that are specific to children (e.g. health effects related fluoride and nitrates in children) or where the dose-response curve is steep (i.e., the difference between the no-observed-adverse-effect level (NOAEL) and the adverse effect level is small. It is recommended that child/adult exposure be included in the potential risk assessment of metals. SAB concluded that the child/adult exposure scenario was sufficiently conservative for risk-based decision-making.

Response>>

See response to Comment B7.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
248 **B37**	10/03/2000	R. Merril Coomes Local Governments	Public Draft - July 2000 3-Section 3	3.2.2	0/31/2000	URS Not Accepted

Comments>

There is considerable discussion in Section 3.2.2 explaining that dermal uptake from water was limited to dissolved metals. However, the recreational beach exposure scenario apparently evaluates dermal uptake of surface water containing "stirred" or suspended sediment. It is not clear, how the beach exposure scenario for dermal exposure to suspended sediment is in agreement with the discussion in Section 3.2.2 and should be explained.

Response>>

Section 3.2.2 discusses pathways excluded from quantification. The dermal pathway for water was not quantified.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
249	10/03/2000	R. Merril Coomes	Public Draft - July 2000		0/31/2000	URS
B38		Local Governments	3-Section 3	p.3-25		Accepted

Comments>

Page 3-25 states that inhalation Screening Values (SVs) were estimated using the particulate emission factor (PEF), as discussed in Section 2.4.1. Section 2.4.1 does not discuss PEF or how they are applied in this risk assessment.

Response>>

Page 3-25 contains a typographical error. Section 2.4.5 should be referenced rather than 2.4.1. The error will be corrected in the next version of the HHRA.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
250	10/03/2000	R. Merril Coomes	Public Draft - July 2000	3.2.3	0/31/2000	URS
B39		Local Governments	3-Section 3			Accepted

Comments>

Section 3.2.3 indicates that dermal absorption of metals is very slow and that “available data indicate that the contribution of dermal soil exposure to overall risk is typically small”. However, the risk assessment appears to be inconsistent with this concept and identifies the dermal contact pathway as a significant contributor.

Response>>

See also response to Comment B15. Discussion will be added to the report to indicate that the dermal contribution to residential exposures is small, but that dermal contribution for neighborhood exposures can be higher because of the increased skin surface area assumptions. However, changing skin surface areas for the neighborhood exposures has little overall affect on risks. A table will be provided to show the dermal contributions to total risks and hazards based on reduced skin surface area.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
251	10/03/2000	R. Merril Coomes	Public Draft - July 2000		0/31/2000	URS
B40		Local Governments	3-Section 3	p.3-35		Partially Accepted

Comments>

Page 3-35. It is indicated that the 95 percent upper confidence limit (95 UCL) was calculated only when the number of samples was greater than 10. FSAP Addendum 05, page 8, which based statistical rationale on the median, identified 7 samples as sufficient to estimate the 95 UCL. What caused the difference in the planned analysis and the Report analysis? This should be discussed in the data evaluation Section, following EPA’s DQA guidance. An EPA citation and statistical rationale are recommended to support the position that 10 samples are too few to calculate a 95 UCL for human health risk assessment use. This position does not agree with Basin Sampling and Analysis Plans or, in general, with other EPA risk assessments. For example, 95 UCL values were calculated for the Spokane River risk assessment, where seven samples were collected at each site. If the decision that supported less than 10 samples were not risk-based, it is possible that the sample results are not appropriate to evaluate potential human risk. This would become clear if the Data Evaluation section used the DQA Process and Data Usability in Risk Assessment Guidance (guidance that is not cited or used in the report).

Response>>

The discussion on page 3-25 explains that a minimum of 7 samples was sufficient to calculate a UCL on beaches because of the relative homogeneity of the beach materials. The number of minimum samples was increased to 10 in the HHRA for non-beach areas because the EPCs were not all from relatively homogenous materials from the same source, as is consistent with the 1992 Supplemental Guidance to RAGS: Calculating the Concentration Term. Some discussion will be added to the text explaining that in only nine of the 49 EPCs calculated was the maximum concentration used because there were fewer than 10 samples, for these nine cases there were also fewer than 7 samples.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
252	10/03/2000	R. Merril Coomes	Public Draft - July 2000		0/31/2000	URS
B41		Local Governments	3-Section 3	p.3-38		Not Accepted

Comments>

Page 3-38 states that there are insufficient data to statistically compare metal concentrations for analyzed soil floor mats and house dust. There are 83 matched data sets for soil and floor mats and 74 matched data sets for soil and house dust. If the hypothesis is whether or not there is a statistical relationship between the soil and floor mat or soil and house dust, there is sufficient information to make a comparison. Note statistics used to support decisions that data sets are the same, for example the Students T statistic, change very little after a sample number of about 30. The reviewer recommends performing the statistical tests and then explaining the resulting relationship.

Response>>

See response to Comment B10. Statistical evaluations were included in Appendix I and discussed in Section 7. There was insufficient data by geographic area, not overall.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
253	10/03/2000	R. Merril Coomes	Public Draft - July 2000		0/31/2000	URS
B42		Local Governments	3-Section 3			Not Accepted

Comments>

The Report expressed concern about the relationship between yard soil and house dust for smaller geographical areas. If smaller areas are of concern and a relationship between soil and indoor dust is expected, the sub area could be tested to determine whether there is a difference between sub areas using nonparametric statistical tests such as the Wilcoxon Rank Sum. There appear to be sufficient data to estimate the uncertainty associated with this assumption.

Response>>

See response to Comment B10. We do not agree that there is enough data in each geographic area to make results of a Wilcoxon Rank Sum test meaningful. In addition, there are other issues regarding the relationship between yard soil and house dust that contributed to the decision not to use the data in the risk calculations. These reasons are discussed in Section 3 and 7.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
254	10/03/2000	R. Merril Coomes	Public Draft - July 2000		0/31/2000	URS
B43		Local Governments	3-Section 3			Partially Accepted

Comments>

The Report assumes that soil is the major contributor to indoor concentrations of chemicals in dust because of the uncertainty in the soil/house dust data relationship. EPA RI/FS guidance states that the objective is not to eliminate uncertainty, but to make confident decisions with acceptable uncertainty in the data. Risks Assessment Guidance states that the quantitative risk assessments are performed when the uncertainty in the estimate is known (EPA 1992). It is recommended that the uncertainty in the relationship between soil and house dust be explained in a manner the public can interpret.

Response>>

The uncertainty in an estimate of concentration change between the soil and house dust data is not known. The HHRA used soil as a surrogate and some of the implications of that choice were discussed. Page 3-38 of the HHRA states "Using soil concentrations as surrogates for house dust concentrations has the potential to either underestimate or overestimate human health risks." Further discussion of this issue was provided in Section 7. The text of Section 3 will be reviewed and clarified.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
255	10/03/2000	R. Merril Coomes	Public Draft - July 2000		0/31/2000	TG
B44		Local Governments	3-Section 3	p.3-39		Partially Accepted

Comments>

Page 3-39 States "The uncertainties regarding the exact relationship between dust and soil concentrations for metals other than lead make predicting a house dust concentration from a soil concentration problematic." This statement appears to assume that lead is transported differently in the environment than other metals and that an exact relationship is required. The acceptable uncertainty for exact should be identified. Differences in transport of lead compared to other metals, should be supported with Conceptual Site Models (and supporting text) that identify the differences between the transport pathways from yard soil to house dust for lead compared to other metals. Note that EPA guidance does not require making exact relationships known. Because paired data are not presented in the Report, the potential relationship between yard soil and house dust, for other metals, cannot be reviewed.

Response>>

We agree that an "exact" relationship is not required. The reference to lead was meant to refer to the fact that lead dust issues have been more extensively studied and there is considerably more data for lead in dust than for other metals. We are not assuming that soil-to-dust transport mechanisms would necessarily be different for lead than other metals.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
256	10/03/2000	R. Merril Coomes	Public Draft - July 2000		0/31/2000	URS
B45		Local Governments	3-Section 3	p.3-39		Partially Accepted

Comments>

Page 3-39 waste pile samples. Exposure to surface material is limited to the top inch of surface material. This boundary condition is described in many parts of the Report and is a basis for considerable data collection related to human exposure. However, it is stated that waste piles contained little or no fine material within the top one-inch and this is the only material (top one-inch) that would be ingested by hand-to-mouth transfer. Because there was insufficient fine material in the top one-inch, bulk "source" samples were apparently taken of the waste rock pile. EPA's risk assessment guidance cautions about using source characterization data for risk assessment. The guidance (EPA 1989, page 6-28) states that care must be taken in using such data (obviously contaminated soil or hot spot areas) to estimate exposure concentrations. EPA indicates that when a source area is included in a risk assessment, that a random sampling plan be used to obtain "source" data for the risk assessment. Data from the waste piles are apparently source characterization samples and are not likely to represent the potential for exposure. The reviewer does not have the FSAP for waste pile characterization. Were the samples randomly collected from the waste pile or judgmentally selected? Does the FSAP indicate that the samples will be used to support risk assessment? If it does, what are the identified uncertainties of using these data? These issues need to be documented in the Report. This comment assumes the samples were judgmentally selected for source characterization. If this is true, these data may not be appropriate for risk assessment. The limitations of using these data should be discussed in the exposure assessment and uncertainties sections.

Response>>

See response to Comment B11 and B12. Samples from waste piles were collected specifically to support the HHRA (FSPA08).

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
257	10/03/2000	R. Merril Coomes	Public Draft - July 2000		0/31/2000	URS
B46		Local Governments	3-Section 3	p.3-40		Accepted

Comments>

Page 3-40. The Report describes floodplain soil/sediment samples as two intervals, the top 12 inches and 0-1 inch. However, data included in Table 1.1, Appendix E and the FSAP, identifies that data were also collected from the 0-6" depth (three individual sample depths).

Response>>

Text will be amended to include discussion of all three depth intervals as are noted in Section 2.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
258	10/03/2000	R. Merril Coomes	Public Draft - July 2000		0/31/2000	URS
B47		Local Governments	3-Section 3	p.3-40		Partially Accepted

Comments>

Although the FSAP provided rationale to support collecting separate depth interval data (evaluating different receptor populations such as campers) the data were combined in the risk assessment for a single receptor. Difference between the rationale used in the Report and that used for data collection should be explained in the Report. The rationale to collect the data separately was provided in the FSAP, but the rationale to support combining the data is not discussed.

Response>>

Text will be added to clarify the reasons data were combined for a single receptor group. See also response to Comment B2.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
259	10/03/2000	R. Merril Coomes	Public Draft - July 2000		0/31/2000	URS
B48		Local Governments	3-Section 3	p.3-40		Accepted

Comments>

Because the actual data are not provided in the Report by depth, it cannot be determined for all cases that combining the data is appropriate. However, a statistical analysis of the data for Blackwell Island is possible because the screening level risk assessment provided the average, maximum, and minimum values for arsenic. Using that information (Pages 49 and 50 of the November 30, 1998 Expedited Screening Level Risk Assessment), the soil and sediment values for different depths can be identified and are shown below:

Blackwell Island Data for Arsenic

□Sediment, 0 to 6” and 0 to 12”□□Upland Soil, 0 to 1”
□Max = 83.4□□Max = 20.3
□Min = 19.8□□Min = 9.7
□19.8□□9.7
□37.2□□12.4
□38.8□□12.5
□39.8□□14.2
□45.8□□15.7
□52.2□□16.7
□53.4□□20.3
□56.7□Average□14.5
□59.2□□
□59.3□□
□63.5□□
□74□□
□77□□
□83.4□□
Average□54.3□□
□□□

A Wilcoxon Rank Sum test demonstrates the two data sets are from different populations (data sets that cannot not be statistically combined) at the 99 percent confidence level. The available data do not allow distinguishing between the 0 to 6’ and 0-12” sediment data. The Report combines these data sets and then proves statistically that the distribution is not log normal and is a normal distribution. The analysis is not meaningful when the two data sets are from different populations. There is concern that sediment and soil data sets have been inappropriately combined for all recreational soil/sediment exposure scenarios. It is recommended that the actual data be summarized in the report to allow reviewers to confirm that combing the data sets is appropriate.

Response>>

Actual data for Blackwell Island were provided in Appendix F; however, the detail with sample number and depth appears to have been inadvertently left out of Appendix E. This information will be added. See also response to Comment B19.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
260	10/03/2000	R. Merril Coomes	Public Draft - July 2000		0/31/2000	URS
B49		Local Governments	3-Section 3	p.3-40		Accepted

Comments>

In addition, the difference between the FSAP and Report, related to data evaluation and receptors, should be explained in the Report.

Response>>

Text will be amended to describe the differences. Also, see response to Comment B2.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
261	10/03/2000	R. Merril Coomes	Public Draft - July 2000		0/31/2000	URS
B50		Local Governments	3-Section 3	p.3-40		Not Accepted

Comments>

Page 3-40 surface water sampling. Two methods were used, one to collect surface water and the other to collect "stirred" surface water. Risk assessment guidance states to evaluate surface water and sediment exposure that both media are collected from the same location. Risk assessment guidance does not identify a "stirred" sampling approach to evaluate exposure. The guidance does indicate that exposure to surface water and sediment occurs at the same time and place. Therefore, sediment and surface water samples should be collected from identical locations at the same time. The stirred sample data may "double count" the risk contribution made by sediment.

Response>>

Sediment and stirred surface water were collected from the same place at the same time. The sediment swallowed in the water represents a separate exposure in addition to the "usual" sediment ingestion during land activities. Therefore, we disagree that there was double counting.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
262	10/03/2000	R. Merril Coomes	Public Draft - July 2000		0/31/2000	URS
B51		Local Governments	3-Section 3	p.3-40		Partially Accepted

Comments>

Page 3-40. It is stated that the fish tissue concentrations used in the risk assessment "likely represents somewhat of a "worst case" for human consumption. EPA policy specifically states that risk assessments are not intended to evaluate worst case exposure scenarios. It is recommended that the exposure scenario be modified to be in agreement with EPA policy. Note that simply changing the description of "worst case" is not appropriate. The exposure parameters or estimated concentrations should be modified for the fish tissue exposure scenario.

Response>>

Fish from the lateral lakes may represents somewhat of a worst case when considering fish from other areas (such as Lake CdA). However, if a person fishes in the Lateral Lakes area, EPCs and exposure parameters are representative of RME exposures. The text will be clarified.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
263	10/03/2000	R. Merril Coomes	Public Draft - July 2000		0/31/2000	URS
B52		Local Governments	3-Section 3	p.3-41		Partially Accepted

Comments>

Page 3-41 Construction site soil. Using all soil data from all depth intervals within a geographical area is not appropriate. This approach dilutes the potential hot spot areas, lowering the estimated risk. In addition, the approach increases the estimated risk at "clean" locations within a geographical area that actually do not pose unacceptable risk. This problem is widespread in the risk assessment for all receptors and adds confusion to risk-management decision-making.

Response>>

We agree with the reviewer that the approach dilutes potential hot spots and overestimates risks to "clean" areas. The goal of risk assessment is to estimate "average" exposures (with an adequate margin of safety) for a specific activity. Construction workers could be moving dirt in both clean and dirty areas; therefore, the estimates are an appropriate representation of potential risks. As we described in our responses to Comment B13 and B14, all areas with potential mining wastes have not been sampled in the Basin; thus, our approach was to examine risk and hazards from exposure to both clean and dirty areas to get an idea of whether the over-all activity might be "risky" or not. Any individual, specific, construction project in the Basin must follow the institutional controls program (ICP) already in place and must collect samples if there is no data. The text will be amended to clarify this point.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
264 B53	10/03/2000	R. Merril Coomes Local Governments	Public Draft - July 2000 3-Section 3	Appendix E	0/31/2000	URS Partially Accepted

Comments>

Residential exposure for the Lower Basin appears to have been based on 4 samples, three from Cataldo and one from Harrison (Table in appendix E). A second table, identified as "Lower Basin Resid SS (1).xls (6/3/00) page 1 through 6" in Appendix A identifies 25 to 28 samples used to estimate the exposure point concentration, depending on the analyte. The sufficiency of these data to support a risk assessment that represents an area of more than 100 square miles (the assumed exposure area for a construction worker) is not clear. The area for decision-making is very large compared to the area actually sampled. It appears that the amount of data collected over the exposure area may be insufficient to evaluate construction worker risk and will result in significant uncertainties related to potential risk and the need for remedial action in the Lower Basin. The Report should identify the uncertainties in the risk estimate based on the limited number of samples.

Response>>

See response to Comment B18. The summary table in Appendix E only provides the EPA-collected data. This table will be modified. The residential data can be found only in Appendix F and is summarized on Table 3-21. 13 homes (not 4) were sampled in the Lower Basin. See also response to Comment B13. The data are representative of the areas sampled and remediation activities will need to collect site-specific data for areas which do not have data. The lack of data for the entire area is due to the size and complexity of the site. Data will have to continue to be collected to support risk-management decision-making.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
265 B54	10/03/2000	R. Merril Coomes Local Governments	Public Draft - July 2000 3-Section 3	p.3-46	0/31/2000	URS Partially Accepted

Comments>

Page 3-46. The most recent average body weight for adult men and women is 71.8 kg (EPA, 1997). It is recommended that the more recent body weight be considered in the risk calculations.

Response>>

The use of 70 kg for average adult body weight is appropriate for the arsenic cancer risk calculations because 70 kg body weight was assumed in the derivation of cancer slope factors and unit risks. For the non-cancer risk calculations, however, we acknowledge that 71.8 kg is the newly recommended body weight in the 1997 EFH and use of 70 kg is a slight overestimation of actual risks. However, the most recent Region 10 RCRA guidance (1998) recommends use of the 70kg body weight and thus, this recommendation was followed in this risk assessment. We note that use of new 71.8 kg body weight would only minimally affect the risk calculations and would not affect the risk conclusions. A discussion will be added to the uncertainty section regarding how the higher body weight might affect risk estimates.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
266 B55	10/03/2000	R. Merril Coomes Local Governments	Public Draft - July 2000 3-Section 3	p.3-47	0/31/2000	URS Not Accepted

Comments>

Page 3-47. The relationship between the average time a worker spends at one job and the central tendency exposure time for a construction worker is not clear. Would it be better to identify 6 years as an exposure assumption, without rationalizing the value? Because the area is experiencing a population decrease, is it likely that construction activities would be less than national average assumptions? Please discuss this issue in the exposure assessment.

Response>>

The 6.6 years is EPA's recommended average time a person spends in one job (Table 15-176 from EFH) while 25 years is the recommended time for RME scenarios. These exposure assumptions are identified as national averages and are not Basin-specific. It is unclear what is meant by "rationalizing the value."

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
267 B56	10/03/2000	R. Merril Coomes Local Governments	Public Draft - July 2000 3-Section 3	p.3-50	0/31/2000	URS Not Accepted

Comments>

Page 3-50. Explain how a water intake of 30 ml/hr is appropriate for "playing" in water. This default intake, 30 ml/hr, actually represents a swimming scenario that assumes the swimmer's head is under water a significant percentage of the time. This value may be excessive for water play. A discussion is appropriate.

Response>>

We agree the value may be an overestimate for water play as opposed to swimming. However, because the risk calculations did not identify this pathway as exceeding health goals no additional discussion was provided in the uncertainty section. No changes to text.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
268 **B57**	10/03/2000	R. Merril Coomes Local Governments	Public Draft - July 2000 3-Section 3	p.3-51	0/31/2000	URS Accepted

Comments>

Page 3-51. The exposure duration of 34 weeks (neighborhood recreational exposure to upland parks and schools), April through November is not consistent with the dermal exposure assumptions that assume shorts, bare feet, and short-sleeved shirts for children ages 4 to 11 years old. The climate in April and November (perhaps October) make the dermal exposure assumptions improbable. Snow and ice are tough on bare feet.

Response>>

See response to Comment B15. Discussion and a table will be added to the uncertainty section indicating how risks and hazards would be lowered by reducing skin surface areas.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
269 **B58**	10/03/2000	R. Merril Coomes Local Governments	Public Draft - July 2000 3-Section 3	p.3-51	0/31/2000	URS Accepted

Comments>

A similar issue is related to the paragraph on page 3-50, Skin Surface Area. Local climate must be considered, especially since it is assumed in the previous paragraph that exposure to yard soil is 270 days each year. The skin exposure frequencies appear to be approaching a "worst case" estimate and are higher than a site-specific upper-bound estimate (RME) recommended in EPA risk assessment guidance.

Response>>

See response to Comment B15. Text will be added, no changes to risk calculations will be made.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
270 **B59**	10/03/2000	R. Merril Coomes Local Governments	Public Draft - July 2000 3-Section 3	p.3-51,2-52	0/31/2000	URS Accepted

Comments>

Page 3-51 and 2-52. A soil (sediment) adherence factor of 0.2 is likely to overestimate the sediment adherence during beach play. The child or adult is in the water part of the time and the water activities would "wash off" the sediment. The exposure times for sediment and water contact are identical and it is likely assumed the exposures are concurrent. Please discuss this issue in the exposure assessment and the uncertainty section.

Response>>

The exposure frequencies for water and sediment differ, being 1 hour for water and 3 or 10 hours for sediment depending on whether neighborhood or public receptors are being considered. However, these exposures are anticipated to occur on the same day. The adherence factor of 0.2 was considered appropriate, particularly for public exposures, because of the likelihood that the majority of the time is spent out of the water. We agree the adherence factor may overestimate exposure for a beach scenario. No additions to the uncertainty section are planned because the pathway did not exceed target health goals or contribute significantly to over-all site risks and hazards.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
271 **B60**	10/03/2000	R. Merril Coomes Local Governments	Public Draft - July 2000 3-Section 3	p.3-53	0/31/2000	URS Accepted

Comments>

Page 3-53. Soil Ingestion Rate. This paragraph indicates that about 300 mg/day is an upper percentile ingestion rate based on the cited study. What is the percentile represented by the "upper percentile" identified in the cited study (90 95, or 99 percentile)? What range of values is included in the qualifier about?

Response>>

Text will be added.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
272 **B61**	10/03/2000	R. Merril Coomes Local Governments	Public Draft - July 2000 3-Section 3	3.4.2	0/31/2000	TG Not Accepted

Comments>

Section 3.4.2 Adult Lead Model. It is stated that "The developing fetus is the most sensitive population for adult worker exposure". This is true, but EPA is responsible for "incidental or unknowing" exposure to lead that is not related directly to their jobs. The Occupational Safety and Health Administration (OSHA) is responsible for protecting worker health when the exposure is directly related to the work performed. OSHA has an acceptable and enforceable blood lead standard, which is 30 ug/dl blood lead. OSHA believes this concentration is protective of the fetus in the workplace. This issue should be discussed to ensure that the public understands that female workers, who are knowingly exposed to lead, are regulated by an OSHA blood lead level of 30 ug/dl. It should be clear for the public that EPA does not have authority over the blood lead levels of workers when knowingly working with lead-containing materials and that the acceptable blood lead level is different than currently discussed in the report.

Response>>

The purpose of the adult blood lead model is to predict PRGs (preliminary remediation goals) and not govern blood lead levels monitored in the workplace. The value of 10 ug/dl used in the model is based on the CDC guidelines to protect the health of children, and is therefore, used as a risk-based value in the model. Also, OSHA does not have a direct conflict with EPA's practice of its adult model for setting PRGs. See also General Response to Comments, #11and #10c.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
273 **B62**	10/03/2000	R. Merril Coomes Local Governments	Public Draft - July 2000 3-Section 3		0/31/2000	URS Not Accepted

Comments>

The exposure assessment section does not discuss or define exposure areas for the receptor populations evaluated. For example, the residential exposure area is approximately ¼ acre or the size of an average residential yard. This value can be site-specifically adjusted depending on the characteristics of the demographic area being evaluated. EPA's SSL guidance evaluates exposure areas of ½ acre and identifies this area as the area to which a decision applies.

Response>>

See response to Comment B13 and others.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
274 **B63**	10/03/2000	R. Merril Coomes Local Governments	Public Draft - July 2000 3-Section 3		0/31/2000	URS Not Accepted

Comments>

The exposure area for the "neighborhood recreational 4 to 11 year-old" should also be defined. For example, it is unlikely that this exposure area would include locations more than two (pick a number for the Report) miles from the residence. As the distance increases from the child's residence, the fraction of time exposed to the evaluated area would be expressed as "FI" (Fraction Ingested from the Contaminated Source) in the exposure algorithm.

Response>>

We agree that neighborhood exposures are likely limited to areas fairly close to home and in general, the sample locations used to evaluate neighborhood exposures are within 2 miles or less of a residence. Because the population is very spread out and the Basin is very large, a potential play area close to one home will be far from another within the same geographical region. The strategy selected was to look at average exposures to sediments, surface water, and waste piles in potential play areas within a region and get an estimate of whether such behavior might be "risky" or not. Adding an FI term under these conditions does not make sense. As described in the response to Comment B13 and B14, actual risk management decisions will be on a site-by-site basis and will take into consideration the concentrations at that spot and the number of residences in close proximity to the area.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
275 **B64**	10/03/2000	R. Merril Coomes Local Governments	Public Draft - July 2000 3-Section 3		0/31/2000	URS Not Accepted

Comments>

Although FI is a critical concept when performing a risk assessment, it is not discussed in the report. Using appropriate FI values would result in a document that is in agreement with EPA guidance and would minimize the existing overestimates of potential exposure. A discussion of FI, as it relates to the defined exposure area for each receptor is strongly recommended in the revised report. A confident risk-management decision cannot be supported without using EPA's FI risk assessment concept.

Response>>

We disagree for this particular risk assessment, see response to Comment B63.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
276 **B65**	10/03/2000	R. Merril Coomes Local Governments	Public Draft - July 2000 3-Section 3		0/31/2000	URS Not Accepted

Comments>

For example, a construction worker in the Lower Basin Area is likely to work in at least a ten by ten mile area (100 square miles). However, data have been collected only for a narrow corridor ten miles long adjacent to the Coeur d'Alene River. Assuming conservatively that collected data represents a width of one mile (note that all sample locations are actually adjacent to the river), only ten square miles have been characterized. Using these assumptions, a FI value for the construction worker would be 0.1.

Response>>

We disagree for this particular risk assessment, see response to Comments B14 and B63.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
277 **B66**	10/03/2000	R. Merril Coomes Local Governments	Public Draft - July 2000 3-Section 3		0/31/2000	URS Not Accepted

Comments>

The Lower Basin risk assessment covers an exposure area that extends approximately 10 miles along the Coeur d'Alene River. If the risk is not acceptable in the Lower Basin along the river corridor and an active remedial alternative was selected, the area requiring active remediation would be the entire area, all 10 miles. Based on the limited data collection and combing sediment and surface soil data, it appears that the confidence associated with applying the results to the entire 10 mile area is low and the decision may not be defensible. There would be a high level of uncertainty in the decision that all of the area requires identical remedial action. Exposure area definition would assist in improving the confidence of the decision for each exposure area that was sampled, but would not provide additional confidence concerning decisions for the entire 10 mile stretch. It is concluded that the risk assessment, as currently structured is appropriate and/or sufficient to support risk-management decision-making for specific and isolated areas of the Lower Basin, but these isolated areas have not been defined or evaluated in the Report.

Response>>

No such decisions treating all of the area the same would be made. See response to Comment B13. The "isolated areas" for the Lower Basin are the common use areas already sampled and identified on the maps currently in the RA.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
278 **B67**	10/03/2000	R. Merril Coomes Local Governments	Public Draft - July 2000 3-Section 3	Figure 3-2	0/31/2000	URS Not Accepted

Comments>

Figure 3-2 shows a declining population of students in the Coeur d'Alene River Basin. This should be taken into consideration when the "future use scenario" is considered. For example, groundwater in side canyons is not likely to become drinking water sources because there is little, if any, population growth pressure to develop those resources. Population decline considerations should be developed and included in the exposure assessment.

Response>>

We do not agree that population decline considerations should be included in the HHRA evaluation.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
279	10/03/2000	R. Merril Coomes	Public Draft - July 2000		0/31/2000	URS
B68		Local Governments	3-Section 3	Figure 3-2		Not Accepted

Comments>

The assumption that groundwater will be used as a drinking water source should be documented using the procedures and rationale given in OSWER Directive 9355.7-04. Based on that Directive, it is unlikely that groundwater use in isolated areas would provide input to risk-based decision-making. If this scenario is to be included in the revised Report, please evaluate the probability of the scenario using guidance from OSWER 9355.7-04 in the Report.

Response>>

OSWER Directive 9355.7-04 does not apply to groundwater as it specifically states at the top of page four "Consideration of future ground water use for CERCLA sites is not addressed in this document." Groundwater is presently being used as a drinking water source in many homes in the Basin, and thus the media is appropriately evaluated under both current and future conditions as part of the residential scenario. In some cases, emergency response actions have been taken by the EPA and local health officials to address groundwater contamination over MCLs being drunk in people's homes. We do not agree that declining population issues affect the risk assessment evaluation of risks and hazards through drinking water although these issues may affect risk management decisions. Risk management decisions are discussed and documented in other reports than the risk assessment.

Groundwater near sources areas in Ninemile and Canyon Creek that is not currently being used as drinking water was also evaluated as a possible future scenario. The results of this evaluation were kept separate from the "baseline" residential risks and presented as potential additional incremental risk.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
280	10/03/2000	R. Merril Coomes	Public Draft - July 2000		0/31/2000	URS
B69		Local Governments	3-Section 3			Not Accepted

Comments>

The Exposure Assessment should discuss each chemical transport pathway and medium identified in the CSM. The discussion of the CSM figures is limited to one brief paragraph at the bottom of page 3-34, which is section 3.2.5. The CSM is central to the discussion of exposure, but is not used in this entire section.

Response>>

The CSM figures are primarily discussed in Section 3.2.1, page 3-24. The discussion on page 3-34 is supplemental. However, the bulk of the fate and transport discussion is in the RI portion of the Basin RI/FS documents and it was not the intent of the HHRA to reproduce those details in the report.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
281	10/03/2000	R. Merril Coomes	Public Draft - July 2000		0/31/2000	URS
B70		Local Governments	3-Section 3	p.3-21,3-22, 3-28 through 3-34		Not Accepted

Comments>

The subsistence lifestyle discussion on pages 3-21,3-22 and 3-28 through 3-34 requires separate CSMs to ensure the public understands subtle differences.

Response>>

We are not clear what "subtle differences" need to be addressed in separate CSM figures for residential and subsistence receptors. We consider the CSMs to sufficiently identify the source of contamination, exposure route, and exposure pathway for each receptor type. The discussions in section 3 mostly distinguish between differences in exposure durations and contact rates, neither of which are appropriately depicted on CSM figures.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
282 B71	10/03/2000	R. Merril Coomes Local Governments	Public Draft - July 2000 3-Section 3	Figures 3-3 through 3-11	0/31/2000	URS Not Accepted

Comments>

These figures require modification to meet human health risk assessment objectives and be consistent with EPA human health risk assessment guidance. CSM developed on geographical or ecological considerations are not appropriate for evaluating human health. Currently the CSMs include information that is not discussed in the report, resulting in very complex CSMs. It is recommended that all information in the figures to the left of the Affected media and Secondary Sources "column" should be removed, with the exception of waste rock piles, which should be include as discussed below. While information included in the CSMs may be useful in the RI Report or during sample collection planning (DQO Process) for the RI/FS, it is not useful in human health risk assessment. Only information that is discussed in the Report should be included in the Figures. If this information is "required", all of the "boxes and arrows" should be discussed in sufficient detail for the public to understand why each "box" is included.

Response>>

We acknowledge that the fate and transport section of the CSM figures contains a great deal of information and that the text summary provided in Section 3.2.1 is relatively brief. We disagree that the figures require modification per EPA risk assessment guidance and no citation as to what specific guidance is being referred to was provided by the reviewer. HHRA guidance (USEPA, 1989, RAGs Part A) does not make any references to the complexity of information that should or should not be reproduced in an HHRA but simply requires that human health pathways be shown from source to receptor. The CSM figures adequately perform this task.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
283 B72	10/03/2000	R. Merril Coomes Local Governments	Public Draft - July 2000 3-Section 3	Figures 3-3 through 3-11	0/31/2000	URS Not Accepted

Comments>

Media that are evaluated in the risk assessment should be in the "Affected media" column, which would be more clearly labeled "source media" for risk assessment.

Response>>

Comment noted. We are leaving the media evaluated in the risk assessment in the "exposure routes" column as sufficiently clear for the purposes of this risk assessment.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
284 B73	10/03/2000	R. Merril Coomes Local Governments	Public Draft - July 2000 3-Section 3		0/31/2000	URS Partially Accepted

Comments>

Data were collected for upland soil in the lower basin, but that medium is not connected to a receptor in the Figure. However, the risk assessment evaluates those data for exposure to recreational receptors.

Response>>

The arrow is missing that connects the "upland soil & flood plain deposits" box under affected media to the soil/sediment box under exposure routes on Figure 3-3. This error will be corrected. See the response to Comment B2 and B4.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
285 B74	10/03/2000	R. Merril Coomes Local Governments	Public Draft - July 2000 3-Section 3		0/31/2000	URS Not Accepted

Comments>

The media being evaluated in the risk assessment includes residential soil, mining waste rock, Upland soil (0 to 1 inch) sediment (0 to 6 inches), sediment (0 to 12 inches), tap water, surface water, groundwater, surface water with "stirred" sediment, homegrown vegetables, fish, and household dust (there may be others). The CSMs indicate that household dust originates from wind erosion of tailings and "concentrates and other wastes". However, the risk assessment assumes the house hold dust is equal to yard soil concentrations. The tailings, concentrates and other waste sources were not analyzed statistically in Section 6.4.1 to validate the CSM assumptions. Because the CSM is a document that changes with additional data collection, it appears that the pathways should be confirmed statistically or removed from the CSM as significant pathways. The risk assessment assumes that household dust is equivalent to residential yard soil. The CSM is not consistent with the pathways evaluated in the risk assessment.

Response>>

The CSMs in Section 3 all show that the sources for household dust are residential soil and fugitive dust. It is true that the sources for fugitive dust are listed as "concentrates and other wastes" and "wind erosion." However, fugitive dust is also listed as an insignificant pathway, hence our statement that soil is the major source of chemicals in house dust.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
286 **B75**	10/03/2000	R. Merril Coomes Local Governments	Public Draft - July 2000 3-Section 3	Table 3-19	0/31/2000	URS Not Accepted

Comments>

The information included in, Table 3-19 identifies the receptors, exposure media and exposure points, but this information is not clearly included in the CSMs. The CSMs would communicate issues more clearly to the public, if they contained only the information included in Table 3-19 (plus transport pathways, release mechanisms and incomplete pathways, as appropriate).

Response>>

We disagree. Although Figures 3-3 - 3-11 are more detailed than one typically sees in a risk assessment, the risk assessment team considers these figures to appropriately reflect the information that is contained on Table 3-19. See also response to Comment B71.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
287 **B76**	10/03/2000	R. Merril Coomes Local Governments	Public Draft - July 2000 3-Section 3	Table 3-20	0/31/2000	URS Partially Accepted

Comments>

Appendix E does not provide residential chemical data and therefore, the exposure point concentrations provided in Table 3-20 cannot be confirmed. This omission of data does not meet EPA's policy of clear and transparent risk assessment reports. How does the public confirm that the exposure point concentrations have been calculated appropriately?

Response>>

Appendix F contains the residential data. Text will be reviewed and may be amended to clarify the location of the data.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
288 **B77**	10/03/2000	R. Merril Coomes Local Governments	Public Draft - July 2000 3-Section 3	Table 3-21	0/31/2000	URS Accepted

Comments>

Table 3-21 indicates that 13 homes were sampled for the risk assessment for the Lower Basin. However, Appendix E Table "Summary of Site Data by Geographical Area for the Baseline Risk Assessment" identifies four residential locations: R007, R025, and R115 in Cataldo, and R144 in Harrison.

Response>>

The Appendix E Table only included EPA data. The table will be corrected. See previous responses on this issue.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
289 **B78**	10/03/2000	R. Merril Coomes Local Governments	Public Draft - July 2000 3-Section 3	Table 3-22	0/31/2000	URS Partially Accepted

Comments>

Table 3-22. Residential Exposure Factors. The reasonable maximum exposure (RME) frequencies for soil ingestion, dermal contact with soil and ingestion of drinking water are 350 days/year. However, the exposure frequencies are 260 days per year for soil ingestion and dermal contact, and 234 days per year for ingestion of drinking water in the central tendency exposure scenario. This is not consistent. If a resident is at home eating yard soil, they are likely drinking household tap water.

Response>>

The methods used to arrive at the CT estimates for these two pathways were different and do not imply that people are in their house for different numbers of days. The soil CT estimate is calculated based on the ground being frozen for that period of time while the water CT value assumes that people spend 8-hours a day away from home (the water value is 2/3 the RME value of 350 days). This issue will be clarified in the text of Section 3.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
290 **B79**	10/03/2000	R. Merril Coomes Local Governments	Public Draft - July 2000 3-Section 3	Table 3-22	0/31/2000	URS Not Accepted

Comments>

Note that 260 days/year exposure frequency for the central tendency scenario is due to snow covering the ground and/or frozen soil that is resistant to sticking to the skin dermally. It is not clear, why this site-specific information does not modify the default RME exposure scenario. Snow cover and frozen ground are reality. The RME scenario becomes a "worst case" exposure scenario when the site-specific factors are not included. Worst case scenarios are not in agreement with EPA risk assessment policy. It is recommended that the RME exposure duration for incidental soil ingestion and dermal contact with soil is 260 days and the average scenario would be less.

Response>>

Exposure to soil both by ingestion and dermally continues during the winter inside the home because soil is still tracked into the house for much of the winter; however, it is not clear how much reduction would occur. Therefore, the RME scenario did not adjust contact downward for winter while the CT scenario assumed no contact. These two assumptions likely bound the actual amounts ingested/absorbed. See also response to Comment A19.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
291 **B80**	10/03/2000	R. Merril Coomes Local Governments	Public Draft - July 2000 3-Section 3		0/31/2000	URS Not Accepted

Comments>

The Report proportions water intake between adults and children over the 30 year period they are assumed to live in one location. This is similar to the proportioning of soil intake where is assumed the child exposure is for 6 years and the adult exposure is for 24 years...However, proportioning water intake between adults and children is not supported by EPA risk assessment guidance. The Report supports proportioning of water intake to be "consistent" with EPA' soil ingestion policy. The EPA policy on soil ingestion is based on documented higher soil intakes and lower body weights for children compared to adults. The ratio of water intake to body weight for children and adults is relatively uniform compared to incidental soil ingestion intake. In addition, water intake for children is not well characterized. Please provide documentation of the rationale to combine adults and children for water intake. The discussion should evaluate the uncertainty associated with estimated child drinking water intake. Should water intake proportioning be included in a revised draft risk assessment, the IEUBK default water ingestion rates for children aged 6 months through 6 years, which ranges from 0.2 to 0.59 liters/day, should be discussed and considered in the Report.

Response>>

Proportioning water intake is used by EPA Regions 9 and 3 when developing PRGs. The HHRA followed those protocols. The EPA PRG calculations reflect the most recent information on childhood exposures, an on-going area of research.
We disagree that there is uniformity of water intake rates in children vs. adults. Children are known to consume water at a higher rate, regardless of how water needs are indexed . The caloric requirement per unit body weight is higher than in adults, and water intake is linked to caloric requirements and physical activity. Generation of more water intake is also indicated by ventilation rate and oxygen intake requirements. We refer the commenter to the paper by Calderon and colleagues in a 1999 EHP article dealing with age-based water intakes in the US and, because of this, increased arsenic intakes in children as a function of body mass. It show US children consume much more water than adults on a body mass basis. We also refer the commenter to the EPA ODW/OGW 6/22/00 Federal Register notice [[65(121)FR38888, 2000]], on proposed arsenic MCL rulemaking, which includes statements that the early , bottle-feeding infant age band is a clear risk group for arsenic is because of the high daily water volume intake per body mass. These two citations and many others, such as the 1984 EPA health assessment document for arsenic, show that there is an inverse relationship between water volume intake and unit body index, e.g., kg body mass, such that the younger the individual, the higher the intake rate.

Ref: Calderon RL, Hudgens E, Le XC, Schreinmachers, Thomas DJ. Excretion of arsenic in urine as a function of exposure to arsenic in drinking water. Environ. Health Perspect. 107:663-667 (1999).

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
292 **B81**	10/03/2000	R. Merril Coomes Local Governments	Public Draft - July 2000 3-Section 3	Table 3-23	0/31/2000	URS Partially Accepted

Comments>

Table 3-23, Neighborhood Recreational Exposure Factors. There are inconsistencies in the exposure durations for soil ingestion and dermal contact. Incidental soil ingestion occurs by hand-to-mouth contact. Children and adults eat dirt by licking their fingers. If dermal contact did not occur, incidental soil ingestion would not occur. However, if dermal contact occurs then it is assumed that incidental soil ingestion occurs. The point of this discussion is explained below for the RME scenario. The Waste Pile exposure parameters assume 17 days for soil ingestion, but 34 days for dermal contact. The Upland Soil ingestion exposure parameters assume 34 days for soil ingestion, but 68 days for dermal contact. The Floodplain exposure parameters assume 21 days for soil ingestion, but 96 days for dermal contact and 96 days exposure to surface water. The report needs to explain how the receptor can be dermally exposed to soil and not experience hand-to-mouth, incidental, soil ingestion. The current exposure parameters overestimate dermal exposure by a factor of two compared to soil ingestion intake.

Response>>

See response to Comment B20.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
293 **B82**	10/03/2000	R. Merril Coomes Local Governments	Public Draft - July 2000 3-Section 3	Table 3-23	0/31/2000	URS Accepted

Comments>

A typographical error in Table 3-23; the exposure duration for the central tendency ingestion of surface water should be 48, not "I".

Response>>

The table will be amended.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
294	10/03/2000	R. Merril Coomes	Public Draft - July 2000		0/31/2000	URS
B83		Local Governments	3-Section 3	Table 3-24		Partially Accepted

Comments>

Table 3-24, Public Recreational Exposure Factors. The same incidental soil ingestion/dermal exposure frequency issue is present for these receptors. For the RME scenario, for example in Parks and Schools, the soil ingestion exposure duration is 34 days each year and the dermal exposure duration is 68 days per year. The floodplain soil/sediment ingestion exposure durations are identical at 32 days, which is consistent.

Response>>

See response to Comment B20.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
295	10/03/2000	R. Merril Coomes	Public Draft - July 2000	5.2	0/31/2000	URS
B84		Local Governments	5-Section 5			Partially Accepted

Comments>

Section 5.2 Methodology for Assessing Cancer Risk.

The last paragraph is confusing and does not appear to agree with EPA's risk assessment guidance and the National Contingency Plan (NCP). The paragraph indicates that cancer risks within the 1.0E-06 to 1.0E-04 (one in 10,000 to 1 in 1,000,000) range will be further evaluated in the FS where risk management decisions will be considered. The reviewer cannot locate this interpretation in the NCP or EPA guidance. The NCP indicates that the goal for cancer risk, when a site is remediated, is the range of 1.0E-06 to 1.0E-04 and the point of departure is 1.0E-06. OSWER Directive (Use of Risk Assessment in Superfund Remedial Actions) states that when the cancer risk is less than 1.0E-04, remediation is not generally warranted unless there is evidence of harm to the environment (EPA OSWER Directive 93355.0-30). The risk characterization section discusses the relationship between estimated cancer risk and the "acceptable cancer risk range". This comparison should be removed from the risk characterization section because this range is only appropriate when discussed as a goal for the cleanup of an area that is being remediated. EPA guidance states that remedial action is not warranted unless the risk is greater than 1.0E-04 (assuming there are acceptable environmental effects). The discussion should compare estimated cancer risk to a risk of 1.0E-04, to be in agreement with EPA guidance and policy. If there are conflicting EPA guidance documents that discuss this issue, please incorporate all guidance in the discussion.

Response>>

Remedial activities may be warranted if risks are less than 10E-4 per both the NCP and the OSWER directive. The commenter notes that the goal of the NCP is cancer risks "within" the 10E-6 to 10E-4 range. The text of the OSWER directive states that "when the cancer risk is less than 1.0E-04, remediation is not generally warranted unless there is evidence of harm to the environment (EPA OSWER Directive 93355.0-30)." The directive includes the word "generally" in this statement to allow for site-specific decisions to be made. The text will be clarified regarding EPA guidance and target risk goals.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
296 **B85**	10/03/2000	R. Merril Coomes Local Governments	Public Draft - July 2000 6-Section 6		0/31/2000	TG Not Accepted

Comments>

Using the Integrated Exposure Uptake Biokinetic (IEUBK) Model to Estimate Periodic Exposure Scenarios
A concern about the methodology used to evaluate blood lead levels using the IEUBK Model is modifying the model to accommodate intermittent exposure. EPA states:

"The IEUBK Model was designed for application to exposure scenarios in which there are long periods of relatively steady exposure, not to acute or relatively rapid sub-chronic exposure scenarios, so that only the slowest transfer compartments affect kinetics on the time scales of interest."(EPA 1994a, page 9-16, Report Reference Section 9.0).

The Report simply identifies this issue but does not explain the rationale that supports using the Model although this limitation is clearly stated. It is recommended that a discussion be included in the Report identifying the limitations of the IEUBK Model when attempting to evaluate periodic exposure.

Response>>

See response to Comment B22 and General Response to Comments, #9a, #5a, and #5b.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
297 **B86**	10/03/2000	R. Merril Coomes Local Governments	Public Draft - July 2000 6-Section 6		0/31/2000	TG Not Accepted

Comments>

Lead Intake from Other Sources

OSWER Directives 9355.4-12 and 9200.4-27P indicate that other lead sources should be evaluated. The directives identify interior and exterior lead based paint, air, water, interior lead-based paint etc. The Directives also indicate that sources that may contaminate soil if the soil were remediated should be considered. It is not clear that the Directives provide guidance to evaluate sources of lead that are "remote" from the yard. For example, beach soil/sediment for campers and water sports does not appear to have high potential to contaminate yard soil for much of the Basin. It is not clear that it is appropriate to combine these sources with residential yard evaluation. This issue should be addressed in the Report. It is clear that specific areas (beaches) should be evaluated on their own to determine the potential for unacceptable exposure.

Response>>

Two types of soil exposure outside the home yard are considered in the lead portion of the HHRA. Community-wide soils are considered in the Box Model as part of the residential baseline. These are soils in the neighborhood or larger community that children access in the course of their everyday activities. Other soils outside the residential baseline are considered as incremental exposures. Incremental lead intake rates refer to the amount of lead taken into the body during activities in which only certain members of the population engage. These individuals either consume more soil, dust, water, or food, than the general population or those media have higher lead content. These activities take place outside of the baseline residential environment. Both the consideration of soils from sources other than the yard and the analysis of incremental exposures is consistent with OSWER guidance. These items are reviewed in the Technical Review Workgroup for Lead comments. The Technical Review Workgroup for Lead endorses the methodology but believes incremental exposures are underestimated due to the averaging time used in the analysis. See also General Response to Comments, #3, #5, and #8.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
298	10/03/2000	R. Merril Coomes	Public Draft - July 2000		0/31/2000	TG
B87		Local Governments	6-Section 6	Table 6-32b, 6-33b		Not Accepted

Comments>

The calculation of yearly average lead intake overestimates the annual daily lead intake for receptors. An example is explained below for the soil ingestion intake for children at upland parks. Table 6-33b calculates the child intake from these potential source areas for the Reasonable Maximum Exposure scenario. The exposure scenario for the Upland Parks indicates that a child would be present two times each week for 34 weeks. This is a total exposure of 68 days in one year. The Upland Parks calculation in Table 6-33b for lead at 6,000 mg lead per kg of soil (mg/kg) shows a daily intake of 257 ug (micrograms)/day. This value is used to estimate the intake averaged over the year, which is 168 ug/day in the table. An annual intake of 168 ug/day actually assumes that the number of days at the Upland Park was approximately 238 or 7 days/week for 34 weeks in the year. The correct formula to estimate the average daily lead intake on an annual basis is:

Average Annual Daily Lead Intake (µg/day)Ave = Daily Intake (µg/day) X Number of Days at Upland Parks per Year Divided by the Number of Days in a Year

Because the child's daily lead intake, at 6,000 mg lead per kg of soil (mg/kg) is 257 ug/day and the exposure is 68 days per year at the Upland Park area, the average annual daily lead intake is:

Average Annual Daily Lead Intake = (257 µg/day) * (68 days at Upland Parks/Year) divided by 365 days/year = 47.9 micrograms lead per day (ug/day).

This value is more than three times less than the 168 ug/day given in Table 6-32b. Similar overestimates are given in the tables for beach sediment, waste piles, and neighborhood sediment. For example, the average annual lead intake for waste piles, assuming 6,000 mg/kg lead, is 2.4 ug/day, rather than 17 ug/day given in Table 6-32b.

Response>>

The HHRA disagrees with this comment as it is inconsistent with the methodology employed in the HHRA. The Reasonable Maximum Exposure (RME) Frequency is a 7 hour/day event, two-days per week, for 34 weeks. This totals 476 hours of exposure or 34 equivalent days at 14 waking hours per day. The ingestion rate while engaged in these activities is 300 mg/day. A total of 300 mg/day x 34 days = 10200 mg (10.2 grams) of soil ingested per season or year. At a concentration of 6000 ug/g, (6000 ug/g x 10.2 g) = 61200 ug Pb per year, or 168 g/day as reported in the HHRA. The TRW comments at Section 2.5 provide additional discussion regarding this topic. The Technical Review Workgroup for Lead concludes that the exposure duration is sufficient to include in IEUBK analysis, but believes the risk may be understated, by about 35%, as the exposure should be averaged over 238 days, rather than 365 days. See also General Response to Comments, #5a and #5b.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
299 B88	10/03/2000	R. Merril Coomes Local Governments	Public Draft - July 2000 6-Section 6		0/31/2000	TG Not Accepted

Comments>

Statistical Analysis and Observations

Paint condition is correlated with blood lead, but paint condition appears to be a qualitative variable and not a continuous function. How this affects the analysis and predictability of the correlation should be explained in the Report.
With the large number of samples, it is not surprising that correlation coefficients are statistically significant. However, the calculated correlation coefficients and regression relationships do not imply a causal relationship between the variables. The regression relationships at best explain only half of the variance in the data (R2 = 0.63 2 = 0.49).
The correlation coefficients may be statistically significant (i.e., the confidence interval does not include zero), but the "r" values suggest that the resulting predictive relationship is not significant, because the values are so low (0 < r < 05). In addition, it appears that for a least a few of the correlations, a few high values drive the correlation, which results in relatively high correlation coefficients (for example blood lead (BLBP) versus lead loading rate (LEADLD). It is obvious that, individually, the relationships do not adequately explain variability in blood lead level. Further, because the correlations are so low, none of the resulting regression equations is appropriate for predictive purposes.
Regressions performed using median values for the x-variable should be examined carefully. The Report should discuss whether the median value is a good predictor of the variable it represents.
Correlations in log-space are appropriate only so long as the variables remain as logarithms. If any of the relationships are retransformed to base 10 the correlation coefficient, equation, and other statistics need to be transformed carefully. The relationships cannot be simply transformed.
Overall, the fact that many of the correlations are statistically significant is not a compelling argument. The small r-values, highly scattered data, and low predictive capability of the resulting relationships suggest that the individual variables evaluated are not good predictors for lead blood level.

Response>>

The HHRA disagrees with this comment. The relationship between blood lead levels and environmental exposures is examined throughout the HHRA by a variety of methods. With respect to blood lead levels, regression analysis indicated that dust lead loading rate alone explained nearly 40% of the variation in the dependent variable. Other environmental variables were significant in combination with dust lead loading rate. Those variables were yard soil lead levels, median exterior paint XRF reading, and interior paint condition. Together with age of the child, these variables explain 60% of the variation in blood lead levels. It is well established in the lead health literature that there is an inherent variance in blood lead response among individuals in a population. Considering that this regression model does not address this inherent variance, accounting for 60% of the variation in observed blood lead levels must be considered a strong relationship. See also General Response to Comments #4a and #3a through #3d.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
300 B89	10/03/2000	R. Merril Coomes Local Governments	Public Draft - July 2000 6-Section 6		0/31/2000	TG Not Accepted

Comments>

The multiple regression analysis, which evaluates five variables simultaneously, is somewhat stronger. The analysis of five variables explains 60 percent of the variability in the blood level data is explained with the regression equation. However, 40 percent of the variance remains unexplained.

Response>>

The HHRA disagrees with this comment. See response to Comment B88.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
301 **B90**	10/03/2000	R. Merril Coomes Local Governments	Public Draft - July 2000 6-Section 6	p.6-20, Figures 6-10a-d	0/31/2000	TG Not Accepted

Comments>

It is not clear that the implications of the statistical assumptions and limitations that have been made in the statistical analyses in the Report would be clear to the public.
To minimize confusion between the discussion of correlation for the various parameters discussed on page 6-20 and plotted in Figures 6-10a through 6-10d, it is recommended that the plots contain the correlation coefficient and the line representing the relationship.

Response>>

The HHRA disagrees with this comment. The correlation coefficient (r) can be added to the scatter diagrams, although this is not typically accomplished for presentation of simple correlations and scatter plots and the r values can be found in Tables 6-19 and 6-20. Adding a line to represent the relationship between these variables would more typically be a regression line. However, this may not be appropriate for multiple regression analysis as many of these individual relationships may be secondary in nature.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
302 **B91**	10/03/2000	R. Merril Coomes Local Governments	Public Draft - July 2000 6-Section 6	p.6-30	0/31/2000	TG Not Accepted

Comments>

Page 6-30, Summary Baseline Intake Rates. Explain the rationale for using only the 4-year old child data. The IEUBK Model identifies the intake for each year of age. If this discussion provides meaningful input to the risk assessment, it would be clearer to discuss the entire spectrum of intake than to judgmentally select a specific age group.

Response>>

Four year old intake rates are provided as an example representing the mid-range of age-specific estimates. Other age group estimates are shown in Appendix P and are used in all age-specific analysis in the HHRA.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
303 **B92**	10/03/2000	R. Merril Coomes Local Governments	Public Draft - July 2000 6-Section 6	p.6-32	0/31/2000	TG Accepted

Comments>

Page 6-32, third complete paragraph, discusses the "seasonal" and annual intake of lead and refers to Tables 6-29a-b. The descriptor seasonal is not included on the tables, making interpretation difficult. The text refers to medium exposure rather than central tendency, and this is easily confused with the "medium" to which the receptor is exposed.

Response>>

In the incremental exposure analysis for lead, intakes were estimated for seasonal activities and averaged over the year for input to bio-kinetic models. The EPA TRW review disagreed with this approach in Section 2.4 and 2.5 of the TRW review. The TRW believed that the increment should be averaged over the season. This results in risk being underestimated, according to the TRW, by about 35%. See also General Response to Comments, #5a and #5b. The term medium exposure is potentially confusing and does refer to Central Tendency estimates. The terminology will be modified in the final document.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
304 **B93**	10/03/2000	R. Merril Coomes Local Governments	Public Draft - July 2000 6-Section 6	p.6-31, first para	0/31/2000	TG Not Accepted

Comments>

Page 6-31, first paragraph, provides details about adult blood lead levels and presents data in a table, but then states that the data are not used. Eliminate this table and discussion from the text, and simply state that actual measured blood lead levels are used (Table 6-8b).

Response>>

The table referred to in this comment (Table 6-26) shows adult baseline lead intake rates and not blood lead levels. This table and discussion was added to the HHRA for comparison purposes and to establish that most adult soil/dust intake would be coming from dust.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
305 **B94**	10/03/2000	R. Merril Coomes Local Governments	Public Draft - July 2000 6-Section 6	p.6-31	0/31/2000	TG Accepted

Comments>

Page 6-31 under Occupational Intake Rates identifies three classifications of exposure, nominal, medium, and intensive, and then goes on to state that nominal exposure scenarios are not evaluated in this risk assessment. This is confusing because risk assessments are based on central tendency and reasonable maximum exposure scenarios. Please revise text to conform to EPA exposure scenario definitions.

Response>>

See response to Comment B92.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
306 **B95**	10/03/2000	R. Merril Coomes Local Governments	Public Draft - July 2000 0-Executive Summary		0/31/2000	URS Not Accepted

Comments>
Create two CSMs for the lower Basin, one for the subsistence exposure scenarios and one for other receptors

Response>>
See response to Comment B70.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
307 **B96**	10/03/2000	R. Merril Coomes Local Governments	Public Draft - July 2000 0-Executive Summary		0/31/2000	URS Not Accepted

Comments>
Add waste piles to the risk assessment "source media"

Response>>
Soil in waste piles is already on CSM figures 3-9 and 3-10 (the areas where it was evaluated) as an exposure pathway and the box is connected to various source media such as "waste rock" "tailings", etc. We do not think its addition to source media is necessary.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
308 **B97**	10/03/2000	R. Merril Coomes Local Governments	Public Draft - July 2000 0-Executive Summary		0/31/2000	URS Not Accepted

Comments>
Fugitive dust (as a source medium) has a release mechanism – wind erosion – to provide the rationale for an inhalation intake route.

Response>>
Wind erosion is listed on the CSMs as a release mechanism leading to fugitive dust which is inhaled.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
309 **B98**	10/03/2000	R. Merril Coomes Local Governments	Public Draft - July 2000 0-Executive Summary		0/31/2000	URS Not Accepted

Comments>
Use the conceptual site models in the Report that were used to design data collection. The conceptual site models shown in Figures 3-3 through 3-11 do not agree with conceptual site models used in the July 24, 1998 Field Sampling Plan, Addendum 05. For example, there is not a common use area conceptual site model in the Report, but Figure 1 in the FSAP, addendum 5 clearly shows the chemical transport and receptor relationships used to plan data collection. The CSM shown in Figure 3-4 of the Report and Figure 2 of the FSAP are significantly different, although they have the same objective, which is to collect data and use the data to estimate potential risk for recreational beaches.

Response>>
See previous response to Comment B2 on this issue.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
310 **B99**	10/03/2000	R. Merril Coomes Local Governments	Public Draft - July 2000 0-Executive Summary		0/31/2000	URS Not Accepted

Comments>
Discuss the details of the conceptual site model in the text. The text should discuss chemical transport pathways, define exposure points, define the exposure area, and discuss intake routes. This text supports the figure and clearly explains exposure assessment issues to the public.

Response>>
See response to comment B69.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
311 **B100**	10/03/2000	R. Merril Coomes Local Governments	Public Draft - July 2000 0-Executive Summary		0/31/2000	URS Partially Accepted

Comments>
Deviations from planned data use must be explained in the Report. The planned data use for the "wet" sediment was apparently to evaluate potential exposure to waders and swimmers (FSAP, Addendum 05). The planned data use for soil data, identified as unvegetated Beach/Playground in FSAP, Addendum 05, was to evaluate potential exposure to visitors and campers.

Response>>
The HHRA working group made the decision to evaluate only one recreational receptor rather than several different receptors for these areas. The assumption used was that the receptor would spend equal amounts of time exposed to the sediment and soil. This assumption is considered to be adequately protective given the exposure parameters used to quantify Lower Basin recreational risks. See response to Comment B2.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
312	10/03/2000	R. Merril Coomes	Public Draft - July 2000		0/31/2000	URS
B101		Local Governments	0-Executive Summary			Not Accepted

Comments>

Discuss and define exposure area(s) in the Report for all receptors.

A more detailed analysis of potential risk by exposure area is recommended in the Lower Basin. EPA guidance relates the exposure area to the Scale of Decision Making for surface and subsurface soil (EPA 1996). This means that the risk assessment results contribute to making a decision to select a remedial alternative over a defined area (scale of decision making). These concepts are not identified in the Report and this omission does not allow the risk manager to make an informed and defensible decision.

Response>>

See previous responses on this issue, particularly Comment B13 and B14.

Misc. Input>>

The Lands Council

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
127 **C1**	10/16/2000	Michelle Nanni The Lands Council	Public Draft - July 2000 0-Executive Summary		0/30/2000	URS Accepted

Comments>

First of all, we support that the assessment addresses current as well as FUTURE potential health risk scenarios in the basin.

Response>>

No response required

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
128 **C2**	10/16/2000	Michelle Nanni The Lands Council	Public Draft - July 2000 0-Executive Summary		0/30/2000	URS Accepted

Comments>

We also support the approach of evaluating health risks to both typical Central Tendency (CT) as well high risk Reasonable Maximum Exposures (RME) populations in the basin, including tribal/subsistence populations. We believe that health risks should be remedied and decreased for both the general population as well as those most exposed and at risk.

Response>>

No response required.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
129 **C3**	10/16/2000	Michelle Nanni The Lands Council	Public Draft - July 2000 0-Executive Summary		0/30/2000	TG Partially Accepted

Comments>

With respect to existing blood lead data - gathered throughout the basin in 1996 by the Idaho Department of Health and Welfare and federal ATSDR, along with subsequent blood lead data gathered between 1996 and 1999 - it is apparent that there are significant public health impacts occurring in the basin due to heavy metals contamination. Also, given that the assessment states that approximately 25% of eligible children in the basin participated in the surveys, it appears that the blood lead data set provides an adequate foundation, at this time, for determining health risks and potential remediation scenarios.

Response>>

The HHRA agrees with this comment. The existing blood lead data base is the most reliable information for current risk assessment purposes. However, there are legitimate concerns as to whether these data are representative of non-participants. See General Response to Comments, #2a and #3b.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
130	10/16/2000	Michelle Nanni	Public Draft - July 2000		0/30/2000	TG
C4		The Lands Council	0-Executive Summary			Not Accepted

Comments>

Therefore, based on the existing blood lead data and goals of the assessment, The Lands Council supports the use of the stricter soil cleanup levels for lead (400 mg/kg) estimated by the EPA Default Model, versus the Bunker Hill Superfund Site (BHSS) "Box Model," based on the following points:

* The assessment presents strong reasons why the blood lead data set may actually UNDER-estimate wider childhood exposures in the basin, which justifies a more conservative cleanup level to be achieved in the basin;

* It is unlikely that the consistent high rates of lead poisoning measured among children are due to repeat testing of the same children year to year, because health intervention measures usually correct the problem after a high blood lead level is detected ? therefore further supporting the data set and more protective cleanup levels;

* The assessment concludes that background or pristine environmental concentrations would be required for all media to safely support Native American subsistence activities;

* The assessment concludes that soils with lead concentrations near 500 mg/kg could result in a greater than a 5% probability for blood lead levels higher than 10 µg/dl, for intensive/RME exposures relating to landscapers, farmers, and agricultural workers, as well as remediation and construction workers;

* The BHSS "Box Model" uses site-specific data based on 1000 mg/kg residential yard cleanup level for lead, but a 350 mg/kg COMMUNITY-WIDE average overall for soils - which is contrary to the cleanup levels proposed by the Box Model for the rest of the basin in this assessment;

* The assessment shows that the Box Model underpredicts actual blood lead levels for most geographical sub-areas in the basin, particularly the Lower Basin area.

In summary, given the above points and the strong evidence of high rates of health impacts occurring in the basin, we strongly urge that the more conservative health cleanup thresholds predicted by the EPA Default Model be applied in the basin for remediation purposes. For the reasons stated above, we do not find sufficient evidence that the Box Model predictions and recommendations would provide adequate protection for public health in the basin ? for present or future populations.

Response>>

The HHRA disagrees with this comment. It is not known if the available blood lead data over-estimate, under-estimate or accurately portray the non-participants in the health surveys. The Box accurately predicts observed blood lead levels in the upper Basin. The Box Model has performed well at the BHSS, and there is reason to believe that similar pathways and dose/response relationships could apply in the upper Basin. Risk managers should not discount the potential applicability of this model in their consideration. See also General Response to Comments, #2a, #3b, #4a and #9.

Misc. Input>>

Shoshone Natural Resource Coalition (SNRC)

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
109	10/15/2000	Kathy Zanetti	Public Draft - July 2000		0/30/2000	TG
D1		SNRC	8-Section 8	p.8-3,8-4		Partially Accepted

Comments>

1. In the Summary and Conclusions, pages 8-3,4:

The presentation of economic data overemphasizes tourism and understates the importance of mining in the economy of Shoshone County. The reported 58% decline in mining employment between 1990 and 1996 reported does not reflect the 250 jobs created at Coeur Silver Valley Operations and the Lucky Friday Mine between 1995 and 2000. Mining is still responsible for 40% to 50% of the economic activity in Shoshone County. Tourism presents an opportunity to increase the economic base and should not be portrayed as a replacement of industrial wage employment.

Response>>

The HHRA agrees with this comment.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
110	10/15/2000	Kathy Zanetti	Public Draft - July 2000		0/30/2000	TG
D2		SNRC	8-Section 8	p.8-3,8-4		Partially Accepted

Comments>

Also we would like to note the difficulty of growing any business segment during a 25 year Superfund project. The State approach of a 25 to 30 year Public Works Project will be much more beneficial to development of a local economy capable of maintaining the remedy.

Response>>

The HHRA agrees with this comment.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
111	10/15/2000	Kathy Zanetti	Public Draft - July 2000		0/30/2000	TG
D3		SNRC	8-Section 8	p.8-5		Partially Accepted

Comments>

1. In the Summary and Conclusions, page 8-5:

- In the July 1999 follow-up of 50 children with blood lead > 10 ug/dl: How many (%) of the children's homes were built before 1960 and before 1940?

Response>>

The July 1999 nurse visit follow-up targeted 28 children (see Table 6-1), with 25 completed because three children moved out of the area. There were a total of 58 children targeted for follow-ups, and 50 follow-up surveys completed for all years combined. Of those 25 completed in 1999, 11 (44%) of the children lived in homes built before 1960, and of those 11, 7 (28%) lived in homes built before 1940. The reasons for high blood leads for those 11 children were mostly attributed to high soil and dust and not necessarily due to lead based paint.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
112	10/15/2000	Kathy Zanetti	Public Draft - July 2000		0/30/2000	TG
D4		SNRC	8-Section 8	p.8-5		Not Accepted

Comments>

1. In the Summary and Conclusions, page 8-5:

- In the July 1999 follow-up of 50 children with blood lead > 10 ug/dl: What was the correlation between yard soil, house dust and blood lead?

Response>>

Using the 58 blood lead observations above 10 ug/dl, there was no significant correlation with yard soil lead concentrations. This result is expected as this subset of the population represents children with high blood lead levels and high soil lead exposures. Correlations with other variables showed some significance, however, the number of matching observations was very low (n is less than or equal to 20). This sample size is too low to yield statistically meaningful estimates.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
113	10/15/2000	Kathy Zanetti	Public Draft - July 2000		0/30/2000	TG
D5		SNRC	8-Section 8	p.8-5		Partially Accepted

Comments>

1. In the Summary and Conclusions, page 8-5:

- In the July 1999 follow-up of 50 children with blood lead > 10 ug/dl: What was the mean income of the families?

Response>>

The survey was a health based survey that was used to help identify possible exposure pathways. Family income level was not a question asked during the survey.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
114 D6	10/15/2000	Kathy Zanetti SNRC	Public Draft - July 2000 0-Executive Summary	P.8-5	0/30/2000	TG Partially Accepted

Comments>

The HHRA and Risk Managers need to pay more attention to social economic factors than a traditional Superfund project, the end goal must be a Lead Safe community, not necessarily a lead free community (see page 3 of the executive summary).

Response>>

The HHRA agrees with this comment.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
115 D7	10/15/2000	Kathy Zanetti SNRC	Public Draft - July 2000 8-Section 8	p.8-4	0/30/2000	TG Partially Accepted

Comments>

The Silver Valley has twice as many pre-1940 housing units as the State average (see page 8-4 of the Summary and Conclusions)

Response>>

The HHRA agrees with this comment.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
116 D8	10/15/2000	Kathy Zanetti SNRC	Public Draft - July 2000 8-Section 8		0/30/2000	TG Partially Accepted

Comments>

The percentage of children living in poverty is twice as high as the state average

Response>>

The HHRA agrees with this comment.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
117 D9	10/15/2000	Kathy Zanetti SNRC	Public Draft - July 2000 8-Section 8		0/30/2000	TG Not Accepted

Comments>

The Silver Valley demographics are similar to national demographics associated with childhood blood lead levels 3 times the clean-up goals.

Response>>

The HHRA disagrees with this comment. It is not possible to make direct comparisons between the Silver Valley and demographic stratifications included in the NHANES national blood lead data base. It is, however, clear that demographic and socio-economic factors play an important role in the degree and incidence of lead poisoning in both the Silver Valley and the nation. See the discussion in Section 6.2.2 of the HHRA. See also General Response to Comments, #1a.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
118 D10	10/15/2000	Kathy Zanetti SNRC	Public Draft - July 2000 8-Section 8		0/30/2000	TG Not Accepted

Comments>

A traditional Superfund approach with the focus on yard removal is much too narrow in scope to make the Valley lead safe. The HHRA uses a simplistic model to justify what appears to be a predetermined conclusion that yard removal is the exclusive answer to elevated blood lead levels in children.

Response>>

The HHRA disagrees with this comment. Analysis conducted in the HHRA suggest that yard soils are a primary source of lead absorption among children both through direct contact and as a contributor to lead in house dust. Other sources, including lead paint, are also identified as sources to both blood and dust lead. The HHRA concludes that both sources present excessive risk and provides example analysis regarding potential cleanup criteria.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
119 D11	10/15/2000	Kathy Zanetti SNRC	Public Draft - July 2000 8-Section 8	p.8-18	0/30/2000	TG Not Accepted

Comments>

The testing data is not considered representative. Panhandle Health is trying to find children with highest blood leads for health intervention reasons, that's why they test in August when the highest levels are expected. (page 8-18) Blood lead levels are known to have a seasonal relationship and the highest occur in August when the sampling is scheduled

Response>>

The HHRA disagrees with this comment regarding the representativeness of the blood lead data. These data are believed to be representative of the participating population, as the peak seasonal blood lead period is purposefully sampled. It is unknown if these data are representative of those Basin residents who did not participate. See also General Response to Comments, #2a.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
120	10/15/2000	Kathy Zanetti	Public Draft - July 2000		0/30/2000	TG
D12		SNRC	0-Executive Summary			Not Accepted

Comments>

The HHRA includes multiplying safety factors: All these safety factors combine and when applied to only one remedy, soil removal, require lower and lower action levels for soil, well beyond the level of diminishing returns.

Response>>

The HHRA disagrees with this comment. Lead health risk assessment applies fewer safety factors or lower margins of safety than typical sub-chronic non-carcinogenic risk assessment methods for other metals. The HHRA does not suggest a single remedy. See response to Comment D10.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
121	10/15/2000	Kathy Zanetti	Public Draft - July 2000		0/30/2000	URS and TG
D13		SNRC	0-Executive Summary			Not Accepted

Comments>

- High end ingestion rates have been assumed for all scenarios
- Whole fish scenarios
- Shallow well scenarios

Response>>

The HHRA disagrees with this comment. These are reasonably expected scenarios for particular populations.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
122	10/15/2000	Kathy Zanetti	Public Draft - July 2000		0/30/2000	TG
D14		SNRC	0-Executive Summary			Not Accepted

Comments>

Using the 10 ug/dl level for adult occupations (constructions, earthwork) when the OSHA standard is 30.

Response>>

Please see response to Comment B61 and General Response to Comments, #10.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
123	10/15/2000	Kathy Zanetti	Public Draft - July 2000		0/30/2000	URS and TG
D15		SNRC	0-Executive Summary			Not Accepted

Comments>

Exposure to waste rock piles is greatly overestimated because of the way samples were collected, the lack of silt sized materials and the outrageously high assumptions of exposure time for children.

Response>>

Incremental exposure factors for waste piles do not distinguish among waste pile types and surface characteristics. Incremental intake rates were developed for both members of the population, one for the typical (Central Tendency (CT)) and one for the reasonable maximum exposure (RME). Estimating the intake rates is a relatively straight-forward procedure utilizing exposure factors developed elsewhere in the document. Generally, these factors are linear and intake estimates are proportional to exposure point concentrations, contact times, and exposure frequencies. Should risk managers disagree with the underlying assumptions or wish to consider alternative factors, the incremental intake rates can be adjusted accordingly. This option is discussed in more detail in General Response to Comments, #5 and #5a.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
124	10/15/2000	Kathy Zanetti	Public Draft - July 2000		0/30/2000	TG
D16		SNRC	0-Executive Summary	p.ES-3		Partially Accepted

Comments>

In the executive summary (ES-3) it is inferred that 25% of the eligible children participated in the blood lead surveys when in fact 1999 is the only year that level of participation was even approached.

Response>>

The HHRA agrees with this comment. It is estimated that there are between 1000 and 1100 children from 9 months through 9 years of age in the Basin area. In 1999, 272 or slightly more than 25% of these children were tested. In four years, 424 of approximately 1300 eligible children have been tested at least once, or about 33%. In other years, less than 10-20% of children were tested. In the Bunker Hill Superfund Site participation rates of the eligible population have been estimated from 42% to 58% annually over the last decade. See also General Response to Commments, #2a.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
125	10/15/2000	Kathy Zanetti	Public Draft - July 2000		0/30/2000	TG
D17		SNRC	0-Executive Summary			Not Accepted

Comments>

If the IEUBK model doesn't reasonably represent the observed data, it should not be used to set action levels. Why not use observed results? The action level used within the Bunker Hill Box is on track to achieve the clean up goals of less than 5% of the at-risk population >10 ug/dl and none above 15 ug/dl. Also note that the average yard lead levels in Kellogg, Wardner and Smelterville were 3 to 4 times higher than those observed outside the "Box" before remedial action.

Response>>

The HHRA disagrees with this comment. The Box Model effectively predicts both mean blood lead levels and percent of children to exceed 10 ug/dl in the upper Basin, in a manner consistent with its performance in the BHSS over the last decade. Risk managers could consider the Box Model appropriate to characterize risk in the Basin provided that similar pathways and dose-response relationships are involved and that the blood and environmental lead levels evaluated in the model are representative of the Basin population. There are questions as to whether the observed blood lead levels are representative of the overall Basin population. Site-specific regression analysis relating blood lead and environmental lead levels suggest similar pathways, with somewhat lower slope values for soil and dust concentrations in the Basin, compared to the BHSS. See also General Response to Comments, #9.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
126	10/15/2000	Kathy Zanetti	Public Draft - July 2000		0/30/2000	TG
D18		SNRC	0-Executive Summary			Partially Accepted

Comments>

Let us be clear and unequivocal. We live in the study area, and nothing is more important to the members of the Shoshone Natural Resources Coalition than the health and welfare of our families, friends and neighbors. We have generations of observations to support our conclusion that the vast majority of the residential areas outside of the Bunker Hill Box are safe, healthy places to raise a family. We simply can't reconcile the extrapolated, projected conclusion, with layer upon layer of safety factor, presented in the HHRA, with the reality of life in most of the Silver Valley.

We challenge you to look beyond the status quo approach and work with the community towards meaningful risk management.

Response>>

The HHRA recognizes the communities commitment to public health and agrees that the involvement and acceptance of the community is critical to the success of any risk management strategy that might be adopted. The HHRA disagrees that inappropriate "safety factors" have been applied. The methodologies employed for lead risk assessment are considerably more complex than those applied in non-carcinogenic risk assessment for other contaminants, and results in more precise, and less uncertain, estimates of effects than is typically obtained. As a result, lower margins of safety are employed in sub-chronic lead risk assessment than in the methods used for other metals. See also General Response to Comments, #9a.

Misc. Input>>

Citizens Against Rails-to-Trails (CART)

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
5	10/06/2000	CART	Public Draft - July 2000		0/30/2000	TG
E1		Citizens Against Rails-to-Trails	0-Executive Summary			Not Accepted

Comments>

The HHRA is a flawed document which states clearly that heavy metals contamination is very dangerous to human health, yet there is no data to support conversion of the contaminated Union Pacific right-of-way (ROW) into a recreational trail. In fact, HHRA data documenting dangers to human health from contaminants (lead, arsenic, cadmium, zinc) suggests that humans should avoid such exposure, since "safe" levels are difficult to determine, and would be, ideally, no exposure at all.

Response>>

The HHRA disagrees with this Comment. Consideration of potential recreational and occupational exposures associated with the Rails-to-Trails conversion are subsumed under the recreational and occupational scenarios considered in the HHRA. The types of activities anticipated for trail users and workers are accounted for in the scenarios addressed in the HHRA. An extensive discussion of demographics and land use is included in Section 3.1, additional characterization can be found in the RI/FS. See also General Response to Comments, #5.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
6	10/06/2000	CART	Public Draft - July 2000		0/30/2000	TG
E2		Citizens Against Rails-to-Trails	0-Executive Summary			Not Accepted

Comments>

Further, HHRA descriptions of resident population, land-use, and ownership are distorted, omitted entirely, or skewed to support use of the abandoned UP ROW as a recreational trail.

Response>>

See response to Comment E1.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
7	10/06/2000	CART	Public Draft - July 2000		0/30/2000	TG
E3		Citizens Against Rails-to-Trails	0-Executive Summary			Not Accepted

Comments>

Additionally, the HHRA is a confusing document, rife with double-talk and allusions to solutions that will be dealt with under "Risk Management" or to problems that will be assessed and cleaned up as they are discovered. We assert strongly that this remedy is totally unsatisfactory, particularly along the abandoned Mullan to Plummer UP ROW.

Response>>

See response to Comment E1.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
8	10/06/2000	CART	Public Draft - July 2000		0/30/2000	TG
E4		Citizens Against Rails-to-Trails	0-Executive Summary			Not Accepted

Comments>

The HHRA documents and underscores the inescapable, hypocritical paradox C.A.R.T. members have been asking EPA to explain for years: How can EPA demand rigid cleanup in the Superfund area and then invite the public to recreate on contaminated land to which they would otherwise not come?

We, members of C.A.R.T., continue to assert that our voices have not been heard, and our right to responsible CERCLA cleanup of contamination left by a known PRP, Union Pacific, has been blatantly compromised. The HHRA essentially denies C.A.R.T. members, as well as the general public, the right to protection of the public welfare guaranteed by EPA. Although the HHRA documents that it is, indeed, extremely dangerous for people (particularly children and pregnant women) to be near contaminants like lead, arsenic, cadmium, and zinc, the Governments continue to invite the public and Basin residents to recreate in a highly contaminated area. This is preposterous! The major fallacy, inviting the public to an area that they would otherwise avoid, is not addressed in the HHRA, nor has it been addressed in any previous documents endorsed by EPA. The increased contamination exposure risk to local residents inherent in the proposed recreational trail has not been adequately addressed. In short, the HHRA, like all other EPA sanctioned documents, circumvents the serious contamination caused by Union Pacific.

Response>>

The HHRA disagrees with this Comment. The government does not invite people to recreate on contaminated properties. The risk management plan adopted for the trail addresses the areas likely to be accessed on the right-of-way. Within 1000 feet of any residence the entire right-of-way will be provided with a clean surface. This addresses the nominal aspects of recreation associated with the residential scenario. At all major access points, sidings and select oasis locations are scheduled for a right-of-way-wide clean up, and large oases are strategically placed along the trail to provide clean rest and stop-and-view areas. In remote contaminated areas, warning signs will be posted to alert trail users of areas presenting excessive risk similar to warnings to avoid local hazards in numerous venues. The signage is provided to both advise users to avoid undesirable areas and to identify safe areas to recreate. See also General Response to Comments, #5.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
9	10/06/2000	CART	Public Draft - July 2000		0/30/2000	TG
E5		Citizens Against Rails-to-Trails	0-Executive Summary			Not Accepted

Comments>

The HHRA, further, relies upon hypothetical future scenarios while omitting reference to the critical danger involved in current scenarios which invite the public to recreate on land so highly contaminated that warning signs and other "institutional controls" must be posted along the proposed trail.

Response>>

The HHRA disagrees with this Comment. The government does not invite people to recreate on contaminated properties. The HHRA recognizes that public beaches and other common use areas throughout the Basin and including railroad right-of-way are routinely used by members of the public. That was one criteria for sampling these areas for the HHRA assessment. Incidents of excess lead exposure have been attributed to common use areas in the Lower Basin. There are numerous public access areas throughout the Basin that will be assessed in the development of a Proposed Plan for clean up. In remote contaminated areas warning signs will be posted to alert trail users of areas presenting excessive risk similar to warnings to avoid local hazards in numerous venues. The signage is provided to both advise users to avoid undesirable areas and to identify safe areas to recreate. See also General Response to Comments, #5.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
10	10/06/2000	CART	Public Draft - July 2000		0/30/2000	TG
E6		Citizens Against Rails-to-Trails	0-Executive Summary			Not Accepted

Comments>

The inadequacy of signs has been acknowledged by the Governments, yet this "control" is expected to keep people on the 10-foot wide strip of asphalt, away from the unremediated contamination bladed off to either side. This contamination will be redistributed during seasonal flood events. Airborne distribution, through dust particles, will further expose the public to contaminants.

Response>>

The HHRA disagrees with this Comment. The governments believe the signage proposed for the trail to be adequate. Contaminated ballast will be graded under the asphalt cap. Some areas of the right-of-way will be subject to flooding as will several other common use areas in the Lower Basin. In areas near residences, sidings, oases, access points and developed recreational areas will be right-of-way-wide, not ten feet wide. Access controls and signage are proposed to warn people of the potential hazards.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
11	10/06/2000	CART	Public Draft - July 2000		0/30/2000	TG
E7		Citizens Against Rails-to-Trails	0-Executive Summary			Not Accepted

Comments>

Landowners along the ROW in the lower CdA Basin between Black Lake and Chatcolet have documented levels of lead as high as 10,300 ppm, arsenic as high 310 ppm, cadmium as high as 35 ppm, and zinc as high as 18,000 ppm in 27 samples taken at their own expense. Additionally, landowners in the Cataldo area found lead as high as 6,620 ppm, arsenic as high as 161 ppm, cadmium as high as 21 ppm. These samples, taken in areas not tested nor planned for contamination removal, are within the subembankment of the UP ROW below lake or river level. These areas, apparently, are not a concern to the Governments, yet the Army Corps of Engineers (partners with EPA and DEQ) state that "Arsenic exposure can increase cancer risk, cause skin problems, and blood and disorders." Further, the Corps report states that "Cadmium at high levels can severely damage the lungs while lower levels can lead to kidney disease." It further states that "Zinc exposure can cause stomach and digestive problems. It may also interfere with the immune system." The HHRA acknowledges the potential problems associated with recreational exposure, although the detrimental amounts of contaminants considered harmful are unclear. Very likely, no amount of any carcinogen can be considered safe. Yet the HHRA carefully avoids any mention of contaminants south of Harrison, on the Reservation, along the UP ROW. Why is this area omitted from mention?

The ROW in Harrison has been documented to have over 50,000 ppm lead, and this is directly adjacent to the public beach that is located well within the ROW. Yet, no remediation has been planned for this area, and no data exist as to the dangers to humans (particularly children, the most vulnerable) from recreational exposure there. Signs posted in the area (documented by C.A.R.T. photographs) are not a deterrent, and small children continue to make mud pies, build sand castles, swim, and generally play right in this highly contaminated area. What about the arsenic? The cadmium? The zinc? The proposed trail plan states that the ballast contamination above Harrison will be bladed to the side, and a 10-foot strip of asphalt will contain the remaining contaminants. This is an absurd remedy, and the Governments are shirking their responsibility to demand that the PRP, Union Pacific, fulfills its CERCLA obligation. Inviting the public to recreate upon a highly contaminated trail (to which they would not otherwise come) is a violation of the duty to protect public welfare. In fact, the lower Basin child mentioned in C.A.R.T.'s Ombudsman testimony with a blood level of 27 ug/dcl lead in August, has recently tested a dramatically lowered level of 14 ug/dcl. The only variable accountable for the drop is that the child no longer recreates along the contaminated public use areas, including the UP ROW!

Response>>

Low levels of contamination consistent with background levels in northern Idaho communities outside the mining district were found in Harrison and southern Lake Coeur d' Alene residential areas. These concentrations were well below screening criteria. These areas as well as lower lake residences, the City of Coeur d'Alene, Post Falls, and Spokane River front homes were excluded from the human health risk assessment. North of Harrison the clean up plan proposes grading exposed ballast to the center of the right-of-way to be contained under the asphalt cap. South of Harrison ballast will be removed. One of the reasons for removing, rather than capping, contaminated materials south of Harrison is the decreased threat of recontamination from flooding outside the flood plain of the Coeur d'Alene River. Estimated post-remediation soil lead levels on the railroad right-of-way from Harrison to Heyburn State Park average 84 mg/kg. Periodic reviews of the effectiveness of the remedy is required.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
12 E8	10/06/2000	CART Citizens Against Rails-to-Trails	Public Draft - July 2000 8-Section 8		0/30/2000	TG Not Accepted

Comments>

The gross misrepresentation of land in the HHRA, particularly land south of Harrison on the Coeur d'Alene Reservation, is unconscionable. "The Coeur d'Alene Basin (CDAB) in northern Idaho includes Lake Coeur d'Alene and the St. Joe and Coeur d'Alene River drainages that are the ancestral home of the Coeur d'Alene Indian Tribe." (Page 8-1, Summary and Conclusion Section) The description omits mention of the people who own land and live on the Reservation. In fact, the Reservation area, south of Harrison, is all privately owned land, and is not, as characterized in EPA/Governments' documents, "natural resource/recreational use land." In fact, allusions to land south of Harrison or assessments of that land by EPA are non-existent. Rather, EPA/Governments' documents appear to intentionally mislead DOJ and any other agencies or people reading the documents into assuming that this Reservation land is uninhabited "with no statistics available for population density," as stated erroneously in the EE/CA, the primary document from which all subsequent planning emerged. In reality, population statistics are a matter of public record, as noted by CART in comments on the EE/CA and Proposed Consent Decree. These comments have never been acknowledged nor addressed by DOJ or the Governments. It is as if our comments were useless. In fact, our comments, like all comments we have submitted over the past nine years, are virtually ignored. Sending us form "thank you for your comment" letters does not in any way meet EPA objectives to work with the public, as well as insure public welfare.

The above description (located in the Summary and Conclusion, page 8-1) of the Coeur d'Alene Basin includes, rightfully, the lands south of Harrison on the Reservation. The HHRA Introduction, (page 1-1, 1-2, accompanying map) however, is ambiguous in specific reference to, or inclusion of, the Reservation lands. The Basin is described as "including Lake Coeur d'Alene and the St. Joe and Coeur d'Alene River Basins" (page 1-1) Yet on page 1-2, the HHRA states that "The Lower Basin area includes 11 lateral chain lakes and extensive wetlands, located adjacent to the main channel and within the CDA River's floodplain. These marshes and lakes provide an extensive recreational area between the town of Cataldo and Lake Coeur d'Alene. Camping, fishing, boating, swimming, hunting, and wildlife photography/observation are popular activities through out the lower CDAB." There is absolutely no mention of Harrison and the privately owned lands on the Reservation, or of the fact that this land is not open to public recreation ! Further, the HHRA Introduction continues by stating that: " There are no incorporated villages between Cataldo and Harrison at the mouth of the main River. However, there are a few small unincorporated village areas and several rural residences." Again, Harrison and the Reservation lands to the south—all privately owned—are not included in this description. The map on the next page, the "Site Location Map," stops below Medimont and does not include the Basin areas south of Harrison on the Reservation! This serious omission makes it appear to the HHRA reader that the Reservation land is non-populated, "public" land that is not part of the Basin. This area includes the Union Pacific right-of-way, currently proposed as part of the 72-mile recreational trail.

The HHRA continues to portray erroneously the land south of Harrison on the Reservation, and thus, infer that the proposed Mullan-Plummer recreational trail is not on or adjacent to privately owned land. For example, on page 8-2, absolutely no references are included to the land south of Harrison. Instead, the HHRA states: (page 8-2,

Response>>

The HHRA disagrees with this Comment. Extensive demographic information is included in Section 3.1 of the HHRA. Figure 3.1 shows the area included in the discussion including lands as far south as Benewah County. Little or no contamination has been noted on these properties. Estimated post-remediation soil lead levels on the railroad right-of-way from Harrison to Heyburn State Park are low. The proposed remedy was extensively reviewed by a number of public agencies and governments including the EPA, Panhandle Health District, State of Idaho, Coeur d'Alene Tribe, several federal trustee agencies, and the Agency for Toxic Substance and Disease Registry. All have found the risk management and clean up plan to be compliant with pertinent rules and regulations and protective of public health. See also General Response to Comments, #1 and #5d, and specific response to Comment E7.

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type

8-3) "Much of the Basin is rural, undeveloped land. Approximately 32% of Kootenai County and 75% of Shoshone County consist of federally managed lands, primarily National Forests. These areas are rich in natural resources including forests, wildlife, and a number of tributaries and streams that support a variety of aquatic organisms. However, many of these areas are inaccessible due to lack of roads, difficult terrain, or lack of services…….Tourism related to the use of these natural resource areas for recreational purposes has increased significantly over the last two decades and is one of the fastest growing contributors to the local economy." This generalized description is not indicative of the lands south of Harrison on the Reservation, which is all privately owned, nor is it representative of lands up to Cataldo, most of which is also privately owned. The grossly misleading depiction, endorsed by the Governments, justifies the recreational trail-related activities as outlined on page 8-3: "Recreational use of the abundant natural resource areas include riding off-road vehicles, snowmobiling, berry picking, mountain biking, fishing and floating down the CdA River, and cross-country and downhill skiing." What the HHRA fails to add is that these activities (although they do happen) are illegal on much or most of the posted "No Trespassing" private land. Readers of this HHRA are misled into thinking the land is not private land, and therefore, recreational trail-related activities are legal on these lands. The erroneous designation, apparently intentional, supports the conversion of the contaminated ROW into a recreational trail. It does not, however, support the legal rights of adjacent landowners to maintain the integrity of their private land.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
13	10/06/2000	CART	Public Draft - July 2000		0/30/2000	TG
E9		Citizens Against Rails-to-Trails	8-Section 8			Not Accepted

Comments>

Related to this, the HHRA section 8.3 does not include population and demographic statistics for Kootenai County, (south of Harrison) already acknowledged as part of the Basin. Statistics are only included for Shoshone County. This omission suggests there are no homes or people in Kootenai, but this is a blatant falsehood, since every inch of this land (at least south of Harrison) is privately owned and has homes built throughout the area.

Response>>

The HHRA disagrees with this Comment. See response to Comment E7 and E8 and General Response to Comments, #5d.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
14	10/06/2000	CART	Public Draft - July 2000		0/30/2000	TG
E10		Citizens Against Rails-to-Trails	8-Section 8			Accepted

Comments>

And, relating to demographics, why is there no intense discussion of elevated cancer rates in Shoshone County? What about other diseases and conditions which, very likely, could be correlated to heavy metal contamination?

Response>>

A recent analysis of cancer rates in Shoshone County completed since the initial draft of the HHRA has been added and will be included as an Appendix to the HHRA.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
15 E11	10/06/2000	CART Citizens Against Rails-to-Trails	Public Draft - July 2000 8-Section 8		0/30/2000	TG Not Accepted

Comments>

Further, the almost non-existent references to the privately owned lands on the Reservation, and indeed the lack of testing done there, attest to the reality that EPA is not only misrepresenting the land, but also EPA exposes area residents and the general public to unknown risk due to the high levels of unremediated contamination from the Union Pacific right-of-way. Indeed, the "Exposure Subareas" on page 8-7 stop at Harrison. No pertinent data are included for areas on the Reservation except for Native American subsistence scenarios. No data is included nor anticipated relating to residential scenarios pertaining to children and adults who live south of Harrison on or adjacent to the proposed trail. This is an egregious oversight. Some of the most contaminated areas in the entire Basin (verified by samples paid for at landowner expense, since only one sample was taken south of Harrison before the Certificate of Interim Trail Use was issued) are in the abandoned Union Pacific right-of-way. Apparently, pregnant women and young children, the most vulnerable to lead, arsenic and metals poisoning, will not be protected from risk if they live south of Harrison.

Further, potential cancer risks as well as non-cancer illnesses related to metals and contaminants are not a concern on the abandoned right-of-way, where land owners have verified lead levels up to 10,300 ppm and arsenic levels up to 310 ppm. Yet all documents endorsed or created by the Governments agree that no level of arsenic can be considered "safe," and that lead levels must be below 400 or even lower, since no "acceptable" level has been determined by scientists and doctors!!

Response>>

The HHRA disagrees with this Comment. Native American scenarios were conducted only for the Lower Coeur d'Alene River flood plain. Sampling of gathering areas in the St. Joe River drainage showed background levels or no detects for native subsistence media. This sampling report will be an Appendix in the final report. Similarly media contaminant levels in Harrison (excluding the beach) and south on the reservation are low outside railroad right-of-way. See also specific response to Comment E7 and E8 and General Response to Comments #5d.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
16 E12	10/06/2000	CART Citizens Against Rails-to-Trails	Public Draft - July 2000 8-Section 8		0/30/2000	TG Not Accepted

Comments>

The HHRA public recreational scenario "pertains to children and adults who use developed parks and playgrounds, and undeveloped recreation areas, whether they are local residents or visitors from outside the area. Public recreational exposures were quantified separately from residential and neighborhood recreational exposures because of the potential for cross-over Basin travel and the possibility that visitors from outside the Basin could use the public areas." Yet, astoundingly, no data is included relating to landowners who live on or adjacent to the proposed trail! It is as if the Union Pacific land and the adjacent landowners do not exist! Why is the land contaminated by Union Pacific omitted from rigorous EPA accountability for cleanup when, in fact, the contamination levels far exceed those already remediated in Superfund areas, and far exceed EPA Early Action lead levels of 2,000 ppm lead? In addition, this land is not included in the Tribe's action plans for the Reservation as documented where the Tribe states that "the plan doesn't include metals pollution caused by historic mining activity, which is being assessed by the tribe and federal government." (Spokesman Review article by Julie Titone, August 28, 2000) There is absolutely no mention of Union Pacific pollution of lands within the abandoned right-of-way that are far away from the smelters and the mines! We live in these areas, and the HHRA does not contain any data relating how the railroad contamination relates to the intended recreational use along the proposed trail.

Response>>

The HHRA disagrees with this comment. Low levels of contamination consistent with background levels in northern Idaho communities outside the mining district were found in Harrison and southern Lake Coeur d'Alene residential areas. Estimated post-remediation soil lead levels on the railroad right-of-way from Harrison to Heyburn State Park average 84 mg/kg. These concentrations were well below screening criteria. These areas as well as lower lake residences, the City of Coeur d'Alene, Post Falls, and Spokane River front homes were excluded from the human health risk assessment. Extensive analysis of contamination data is from both private property and pubic properties and is included in the HHRA for the upper and Lower Basin. See also response to Comment E7 and E8 and General Response to Comments, #5d.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
17	10/06/2000	CART	Public Draft - July 2000		0/30/2000	TG
E13		Citizens Against Rails-to-Trails	0-Executive Summary			Not Accepted

Comments>

In closing, the HHRA is another one in the series of confusing, erroneous documents submitted by the Governments in support of the proposed trail which is a part of the CdA Basin cleanup. All of these documents have not included reference to the egregious damage done by Union Pacific. Instead, the documents refer to “mine waste,” to contaminants “from the smelters,” to contamination from “ore and mine tailings.” The omission of data documenting contamination directly from the railroad construction and/or the railroad operations and the risks this contamination presents to adjacent landowners and the public, is unconscionable. This is especially true since the stated main purpose of the HHRA is “to determine the extent of heavy metal contamination in environmental media that may expose current or future residents or visitors to the CdA Basin, to evaluate the potential human health risks associated with exposure to those contaminated media, and to provide information for risk managers to evaluate the need for remediated action and development of associated cleanup criteria.” Union Pacific has, clearly, received preferential treatment that leaves adjacent landowners, Basin residents, and the general public at increased risk of health problems from exposure to contaminants. The Governments clearly have placed recreation ahead of public welfare, potential tourism ahead of safety from heavy metal poisoning. C.A.R.T. will continue stringent opposition to the flawed trail plan and the accompanying political grandstanding which divert attention from the central issue: Union Pacific must be held accountable for rigid and thorough cleanup of the highly contaminated right-of-way to which they were granted an easement for railroad purposes only. The proposed trail is unconscionable, and the HHRA certainly lends credence and support to that contention.

Response>>

The HHRA disagrees with this Comment. The heavy metal contamination found in the railroad right-of-way has been identified as mine tailings used in the construction of the line as fill or ballast, ores spilled in transportation activities, or fluvial deposits of mineral industry wastes released to the environment. The risk management plan adopted to address these wastes focuses on areas likely to be accessed on the right-of-way. Within 1000 feet of any residence the entire right-of-way will be provided with a clean surface. This addresses the nominal aspects of recreation associated with the residential scenario. At all major access points, sidings and select oasis locations are scheduled for a right-of-way-wide clean up and large oases are strategically placed along the trail to provide clean rest and stop-and-view areas. In remote contaminated areas warning signs will be posted to alert trail users of areas presenting excessive risk similar to warnings to avoid local hazards in numerous venues. The signage is provided to both advise users to avoid undesirable areas and to identify safe areas to recreate. The proposal was extensively reviewed by a number of public agencies and governments including the EPA, Panhandle Health District, State of Idaho, Coeur d'Alene Nation, several federal trustee agencies, and the Agency for Toxic Substance and Disease Registry. All have found the risk management and clean up plan to be compliant with pertinent rules and regulations and protective of public health. See also General Response to Comments, #5d.

Misc. Input>>

Spokane Tribe

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
324	11/20/2000	Fred Kirschner	Public Draft - July 2000		2/07/2000	TG
F1		Spokane Tribe	0-Executive Summary			Not Accepted

Comments>

1. The title should reflect the geographic scope, technical scope, and the preliminary nature of its findings. The preliminary nature of such findings are rooted in the fact that the BHHRA falls short in evaluating risk to sensitive subgroups [NCP at 40CR300.430 (e)(2)(i)(A)(1)] from all contaminated media [NCP at 40CR300.430 (d)]. This short-fall is rooted in the fact that the nature and extent of contamination in pertinent media (e.g. ground water) has not been adequately delineated and the models used to predict current or baseline risk are inadequate. Both of these problems were foreseeable and should or could have been identified prior to performing the BHHRA.

Although the BHHRA identifies many assumptions employed to generate estimates of risk, EPA cannot assume away the types, quantities, and qualities of data critical to making sound decisions regarding remedy selection [NCP at 400.300.430 (a)(1)(i)]. It is foreseeable that if remedy selection proceeds while relying on this less than comprehensive BHHRA, risk will not have been characterized and irretrievable consequences are likely to be realized.

Response>>

The HHRA disagrees with this comment. The title of the HHRA does reflect the geographic area and scope of the document. The HHRA addresses the geographic area extending from Harrison to Mullan. The area of investigation was determined jointly by the EPA, State and Coeur d'Alene Tribe. Those scenarios, source areas, pathways and routes of exposure examined were comprehensively characterized, evaluated and presented in accordance with the NCP. The results and conclusions of the HHRA should not be extended to other areas or scenarios except as explicitly noted.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
325	11/20/2000	Fred Kirschner	Public Draft - July 2000		2/07/2000	TG
F2		Spokane Tribe	0-Executive Summary			Not Accepted

Comments>

2. The BHHRA appears to mix risk assessment and risk management concepts (see General Comment No.
1) This fact is demonstrated in discussions pertaining to background and PRGs. Risk communicators are not necessarily concerned with the source or party at fault. The public only requests to know the risks involved with specific behaviors or practices.

A better approach would be to characterize the "total risk" (pre-mining baseline risk, incremental risk associated with mining, and incremental risk associated with other anthropogenic actions). Total risk will give the public a better picture of the comprehensive risks from all significant and "insignificant" pathways associated with each scenario describing specific behaviors/practices. Incremental risk associated with past mine waste management practices can then be ascertained once these other equally important components of risk have been determined.

Response>>

The HHRA disagrees with this comment. The purpose and objectives of the HHRA are to assess the potential risk of adverse human health effects associated with contaminated environmental media in that portion of Coeur d'Alene Basin addressed. Risk assessment identifies those contaminants, media, pathways, sources of contamination, routes of exposure, and potential for human intake that could pose unreasonable risk. The risk assessment process does not determine clean up strategies or criteria for contaminated media. In situations similar to the Basin, however, public health authorities have found excess absorption to be occurring and preventative actions are in place. Risk management activities are already underway in the form of a lead health intervention program being locally implemented and focused remedial actions being conducted under emergency authority. The adjacent Bunker Hill Superfund Site (BHSS) has been implementing a variety of clean up actions and risk reduction measures for more than a decade, many of which were the genesis of Basin-related activities. As a result, the HHRA does, to the extent possible, consider and review the information obtained, the relationships observed and lessons learned in the numerous efforts to eliminate lead poisoning among the children of the Silver Valley over the last three decades. See also General Response to Comments, #10a.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
326	11/20/2000	Fred Kirschner	Public Draft - July 2000		2/07/2000	TG
F3		Spokane Tribe	0-Executive Summary			Not Accepted

Comments>

3. Based on historical accounts and technical information, the Spokane Tribe has always believed that the Bunker Hill Superfund facility as defined by CERCLA includes the Coeur d'Alene Basin as well as the shores and uplands of the Spokane River to its confluence with the Columbia River. Due to socioeconomic and political shortfalls (both of which are non-technical in nature), EPA has chosen to segregate the facility based on political boundaries with the BHHRA ending and the Spokane River HHRA starting at the Washington-Idaho boundary.

From purely a technical standpoint, EPA's approach of characterizing risk associated with the facility will only be satisfactory if the calculations of risk consider the entire list of COPCs, each RA scenario, and all pathways throughout the facility. However, today we see a much different approach being applied to the problem at hand. For example, the Draft BHHRA concludes that the Coeur d'Alene Tribal Scenario cannot be evaluated because consumption rates and/or concentrations of COPCs are so high that current Pb models employed to evaluate risks are invalid. The Principal Scientist conducting the BHHRA has stated that given the observed concentrations in only one medium (sediment), the Coeur d'Alene Tribal Scenario "pegs the needle" in the CSM. However, another contractor who is conducting a "Screening-Level" RA (a single medium, single RA scenario for "beach play") concludes that only a few problematic areas have been identified in Washington near the state line and that no further study or data gathering is warranted. In the meantime WADOE performed a two pathway scenario (fish consumption and sediment ingestion) RA which includes a broader suite of COPCs that were not evaluated in the BHHRA or the Spokane River SLHHRA, but probably are present in the basin. The result of the WADOE RA indicates that fish consumption is associated with an undesirable degree of risk.

To make matters worse, the Spokane Tribe commented several times verbally and in writing that EPA is using the Screening Level Risk Assessment Tool inappropriately to prematurely screen-out pathways and COPCs for further study. In short, we believe that results of RA modeling for a subsistence scenario designed for the Spokane Tribe and similar to the one used for the Coeur d'Alene Tribe will indicate unacceptable risk is associated with Tribal use of its natural resources.

Response>>

The HHRA disagrees with this comment. The HHRA is limited to the geographic areas and exposure pathways determined jointly by the EPA, State and Coeur d'Alene Tribe. The results and conclusions of the HHRA should not be extended to Coeur d'Alene Lake or the Spokane River except as explicitly noted. With respect to recreational, occupational and residential exposures to the resident population, most of Coeur d'Alene Lake and Spokane River areas were excluded based on the earlier screening risk assessment. Harrison beach and Blackwell Island were retained for additional consideration in the HHRA. A determination was made that insufficient data were available to assess sport or subsistence fishing in the Lake and downstream tributaries in Idaho. No evaluation of subsistence lifestyles, including the screening level risk assessment, has been accomplished for the Lake or Spokane River areas.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
327 F4	11/20/2000	Fred Kirschner Spokane Tribe	Public Draft - July 2000 0-Executive Summary		2/07/2000	TG Not Accepted

Comments>

4. As stated above in General Comment No. 1, the nature and extent of contamination in pertinent media has not been delineated. The result is that the BHHRA relies on assumptions to develop exposure point concentrations (EPCs). These EPCs are then used to perform calculations regarding HHR. This approach has lead EPA to use HHRA tools to identify the "nature and threat of contamination" (at points) prior to identifying the nature and extent contamination". It is almost as if the BHHRA was conducted to support an Extended Site Investigation or a Hazard Ranking Score.

Mixing risk assessment and risk management concepts as described in General Comment No. 2 above, further compounds delineation of the nature and extent of contamination by eventually setting cleanup levels in which the allowable amount of contamination (set by the HHRA) has been fully allocated to extra-background/residential sources (i.e. mine/mill wastes). The bottom line is that the true nature and extent of contamination from past mine/mill practices as well as other historical anthropogenic actions will need to be delineated in order to enable the stakeholders to determine PRGs. Such PRGs should be much lower than BHHRA Risk Based Concentrations with allowable source-derived allocation of incremental risk determined by policy makers of the involved governments.

Response>>

The HHRA disagrees with this comment. Please see response to Comments F2 and F3.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
328 F5	11/20/2000	Fred Kirschner Spokane Tribe	Public Draft - July 2000 0-Executive Summary		2/07/2000	TG Partially Accepted

Comments>

5. The screening step in the BHHRA does not use subsistence assumptions; therefore, contaminants and pathways that do indeed contribute substantial risk have been screened out.

Response>>

See response to Comment F22. Subsistence assumptions were not used in screening and some additional chemicals might have been selected if they were used. All pathways identified by the CdA Tribe for which data was available were quantified.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
329 F6	11/20/2000	Fred Kirschner Spokane Tribe	Public Draft - July 2000 0-Executive Summary		2/07/2000	TG Partially Accepted

Comments>

6. Lead effects were not added to effects from other contaminants, particularly the neurological effects. The lead goals are not based on a human NOAEL or even a human LOAEL, but rather on a definite and measurable effect in children. Therefore, it is even more important to factor in additional neurotoxicity from other inorganics. Also, we are not sure at this time of the Coeur d'Alene's policy pertaining to acceptable risk associated with lead exposure. However, the acceptable risk criteria in the BHHRA does not meet risk identification policy used by the Spokane Tribe.

Response>>

The HHRA agrees with this comment. Several potential sub-chronic effects of lead are not evaluated as possible additive effects in non-carcinogenic risk assessment for other metals, due to the lack of a reference dose for lead. The non-carcinogenic effects of lead per se, are accounted for in the IEUBK. As a result risk managers should note that risks to particular organ systems due to other metals should be considered a minimum, if lead presents similar end point risks.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
330 F7	11/20/2000	Fred Kirschner Spokane Tribe	Public Draft - July 2000 0-Executive Summary		2/07/2000	TG Not Accepted

Comments>

7. The BHHRA is not really comprehensive given the data gaps and the probability that PCBs and dioxins are also present in the fish and sediment (See General Comments No. 1 and 2, above).

Response>>

The HHRA disagrees with this comment. The HHRA is comprehensive and compliant with the NCP with regard to the geographic areas, exposure pathways scenarios and contaminants addressed. This HHRA does not address PCBs or dioxin. See also General Response to Comments, #10.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
331 **F8**	11/20/2000	Fred Kirschner Spokane Tribe	Public Draft - July 2000 1-Section 1		2/07/2000	TG Not Accepted

Comments>

Specific Comments

Purpose of the BHHRA

1. Page 1-1 says that the RA is a companion document to the RI. The purpose of the RI is to define the "degree and extent" of the contaminant release. The purpose of the RA is to determine the risks associated with "residual heavy metal contamination" in the entire CDARB (minus several units that are excluded without a clear rationale).

Response>>

The HHRA disagrees with this comment. Please see response to Comments F1 through F7.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
332 **F9**	11/20/2000	Fred Kirschner Spokane Tribe	Public Draft - July 2000 1-Section 1		2/07/2000	TG Not Accepted

Comments>

2. Page 1-4 says that "it is important that the HHRA be conducted comprehensively," which needs community definition because the RA is not really comprehensive. See General Comments and comments below regarding screening and the need to be comprehensive).

Response>>

The HHRA disagrees with this comment. Please see response to comments F1 through F7.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
333 **F10**	11/20/2000	Fred Kirschner Spokane Tribe	Public Draft - July 2000 1-Section 1		2/07/2000	TG Accepted

Comments>

Boundaries of the CDARB

1. Section 1.1.1. The Coeur d'Alene River Basin boundaries are incorrect. The Spokane River has been omitted. Other language in this section includes the Spokane River identified as CDARB CSM Unit 5. The reference for the separate analysis of the Spokane River needs to be provided.

Response>>

The Spokane River was not discussed in this section and the text will be revised. Section 2.1 discusses each basin geographical area in detail and includes the Spokane River. Section 2.1.5 specifically addresses the Spokane River and references the screening document which evaluated the Spokane River.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
334 **F11**	11/20/2000	Fred Kirschner Spokane Tribe	Public Draft - July 2000 1-Section 1		2/07/2000	TG Partially Accepted

Comments>

2. Page 1-3. The sediments and tailings in the Cataldo area also migrated past Lake Coeur d'Alene and into the Spokane River.

Response>>

The HHRA agrees with this comment.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
335 **F12**	11/20/2000	Fred Kirschner Spokane Tribe	Public Draft - July 2000 1-Section 1		2/07/2000	TG Partially Accepted

Comments>

3. Page 1-4, Para 4. The sediments did not "possibly" migrate into the Spokane River, they definitely did.

Response>>

The HHRA agrees with this comment

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
336	11/20/2000	Fred Kirschner	Public Draft - July 2000		2/07/2000	TG
F13		Spokane Tribe	1-Section 1			Partially Accepted

Comments>

4. The exclusion of segments for lack of data may result in an underestimation of the nature and extent of contamination as well as the risks (See General Comment No. 2).

Response>>

The HHRA acknowledges and discusses the lack of data in many areas. With regard to exposure areas, scenarios, and pathways addressed, the Coeur d'Alene Basin is extremely large and complex. Early in the planning process, in order to meet public requests, the HHRA was placed on an accelerated schedule to be completed in parallel with the RI/FS. It was recognized that, with the associated time and budget constraints, sampling efforts would be limited. Decisions were made to utilize existing data to the maximum extent practicable, fill major data gaps with focused sampling efforts, and not address all possible data gaps and exposure pathways.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
337	11/20/2000	Fred Kirschner	Public Draft - July 2000		2/07/2000	TG
F14		Spokane Tribe	1-Section 1			Partially Accepted

Comments>

5. Excluding data from the adits on the rationale that the fences will prevent entry of people for all time should be revisited. In fact, adits are attractive nuisances. Intruder risks need to be included, especially for teenagers.

Response>>

The HHRA agrees with this comment. These properties can be evaluated by the incremental methodology provided in the HHRA. Incremental exposures were characterized using typical parameters that are specified in the HHRA. Intakes are calculated in a straight-forward manner proportional to those parameters and media contaminant concentrations. Risk management decisions for recreational or trespasser scenarios will be made on a site-specific basis, that will likely require additional sampling and survey information regarding contaminant levels, access restrictions and ownership. Should risk managers elect to modify risk factor parameters to site specific concerns, intake rates can be adjusted proportionately. See also General Response to Comments, #5b.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
338	11/20/2000	Fred Kirschner	Public Draft - July 2000		2/07/2000	TG
F15		Spokane Tribe	1-Section 1			Not Accepted

Comments>

Environmental Data

1. A separate document is needed that examines all the available environmental data collected over time. The detection limits of methods changed over the decades. The GLP and test methods need to be reviewed. The data are presented in a confusing manner, scattered through several chapters.

Response>>

The HHRA disagrees with this comment. The parent documents referenced in the HHRA and the Appendices provide the information.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
339	11/20/2000	Fred Kirschner	Public Draft - July 2000		2/07/2000	URS
F16		Spokane Tribe	1-Section 1			Not Accepted

Comments>

2. The differences in sampling depths and sieving raises concerns. It appears that soil samples from 1", 6" or 12" were mixed and sieved before analysis, which will alter the results, perhaps dramatically. Since sediment is laid down in layers, mixing up to 12" could dilute the concentration. A study that evaluates the concentration of COPCs as a function of grain size distribution within each CSM is necessary.

Response>>

The sediment layers may have different concentrations; however, risks are calculated based on the average chemical concentrations in a particular media to which people are exposed. The assumption is that when people are using the beaches they are exposed equally to these different depths (due to digging play on the beaches). Therefore, the risk equations appropriately use an average sediment concentration that represents beach exposure to estimate health risks. See also response to Comment B4.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
340 **F17**	11/20/2000	Fred Kirschner Spokane Tribe	Public Draft - July 2000 1-Section 1		2/07/2000	URS Not Accepted

Comments>

3. The rationale for sieving needs to be explained further. Page 1-3 refers to highly mobile and dispersible fine materials (without definition of particle size), while the paper by Kissell et al. on the skin adherence of < 175 um particles is used to justify the method used for environmental sampling. The relation between particle size, concentration (or adsorption), skin adherence, resuspension as dust, mobilization and sedimentation in water, plant and animal uptake, ingestion of all particle sizes, and so on should be explained more clearly.

Response>>

Section 2.2.1, pages 2-6 to 2-7 of the HHRA provides in detail the rationale for sieving and the use of the <175 um particle size for human health risk assessment. Other grain sizes and considerations are used for ecological risk assessment and are considered in the RI and FS portions of the study documents for the Basin.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
341 **F18**	11/20/2000	Fred Kirschner Spokane Tribe	Public Draft - July 2000 1-Section 1		2/07/2000	URS Not Accepted

Comments>

4. The water data is not clearly defined as filtered or unfiltered, or total versus dissolved.

Response>>

All water samples were unfiltered and analyzed for total metal content as described on page 2-11, Section 2.2.1. Both disturbed and undisturbed surface water samples were collected for the subsistence scenarios.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
342 **F19**	11/20/2000	Fred Kirschner Spokane Tribe	Public Draft - July 2000 1-Section 1		2/07/2000	TG Partially Accepted

Comments>

5. The problems with lack of fish data (no samples in the main lake and rivers, and analysis for only 3 or 1 contaminant), garden vegetables tested for only 3 compounds, total lack of animal data, and so on will be problematic in the future if not addressed soon.

Response>>

The HHRA agrees that these media have not been fully characterized at this time.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
343 **F20**	11/20/2000	Fred Kirschner Spokane Tribe	Public Draft - July 2000 1-Section 1		2/07/2000	TG Not Accepted

Comments>

Contaminants of Concern and the Screening Process

1. The COC list includes antimony, arsenic, cadmium, iron, lead, manganese, and zinc, but lead is the only contaminant that carries through the selected exposure pathways. These omissions increase the uncertainty and underestimate the risks.

Response>>

The HHRA disagrees with this comment. All potential COCs for which data are available were assessed according to the pertinent federal guidance. See also General Response to Comments, #10.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
344 **F21**	11/20/2000	Fred Kirschner Spokane Tribe	Public Draft - July 2000 1-Section 1		2/07/2000	URS Not Accepted

Comments>

2. Page 1-2 lists lead, zinc, arsenic, cadmium, silver, gold, copper, cobalt, nickel, sulfuric acid, phosphoric acid and fertilizers as major products (there must be minor products as well). The mine tailings and other materials placed on the Cataldo flats include zinc, lead and cadmium wastes. Aluminum, antimony, and thallium are also mentioned. A table that shows the original 23 contaminants and the reasons they were screened out would be helpful.

Response>>

The chemical screening tables (Table 2 series) in Appendix A provide a complete list of all the analytes for each media. In each subsection of Section 2.5, we note how many analytes were examined for each media and we refer the reader to the applicable tables in Appendix A.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
345 **F22**	11/20/2000	Fred Kirschner Spokane Tribe	Public Draft - July 2000 1-Section 1		2/07/2000	URS Partially Accepted

Comments>

3. The definitions of SV and PRG should be presented in risk terms (i.e., the SV for a contaminant relative to its hazard quotient or 1E-6 cancer level given a particular set of assumptions) should be presented a table. The equation for the SV indicates that they are NOT based on subsistence exposure scenarios. If there were a subsistence-screening step, more contaminants would be COPCs.

Response>>

The SV and PRG were defined according to health risk goals in Section 2.4.5, page 2-17. They are presented on the Table 2 series in Appendix A. We agree that these values were based on residential land use and were not based on subsistence exposures. We acknowledge that the use of subsistence-based screening values might have selected additional chemicals. However, the subsistence pathways were clearly identified as "risky" in the HHRA (these pathways had the highest exceedences over target health goals) and selecting more chemicals to evaluate would not change the conclusions of the report. In addition, the HHRA has appropriately identified the risk drivers for the subsistence pathways. We will revise Section 2.4.5 and the Uncertainty Section to clarify chemical selection with respect to the subsistence pathways.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
346 **F23**	11/20/2000	Fred Kirschner Spokane Tribe	Public Draft - July 2000 1-Section 1		2/07/2000	URS Not Accepted

Comments>

4. The one-contaminant, one-pathway risk levels of 1E-6 or 0.1 may not be acceptable to the affected communities.

Response>>

The HHRA selected COPCs using screening values based on a 1E-6 risk level or an HQ of 0.1. We do not believe that chemicals which pose a risk to the general population were omitted from the evaluation. Once a chemical was selected, the HHRA evaluated risks using a multi-contaminant, multi-pathway approach.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
347 **F24**	11/20/2000	Fred Kirschner Spokane Tribe	Public Draft - July 2000 1-Section 1		2/07/2000	URS Not Accepted

Comments>

5. The arsenic MCL for drinking water will be lowered to 5 ug/L, but the reference dose has not changed yet.

Response>>

The process which has resulted in EPA proposing a lower MCL for arsenic is independent of the process by which the RfD was calculated. Therefore, MCL changes do not necessarily mean RfD changes would be required. The RfD for arsenic was appropriately used in this risk assessment. See other responses to comments on this issue as well as Dr. Paul Mushak's responses on arsenic's RfD.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
349 **F26**	11/20/2000	Fred Kirschner Spokane Tribe	Public Draft - July 2000 1-Section 1		2/07/2000	URS Not Accepted

Comments>

7. If this RA is supposed to be "comprehensive," then at least a few soil and biota samples need to be analyzed for PCBs, dioxins, forestry herbicides, lumber treatment materials (preservatives such as CCA and PCP, creosote and polyaromatics, and so on). With all the logging and mining activity, some gasoline or diesel spills would be expected, too.

Response>>

The scope of the CERCLA response was limited to mining-related contamination in the Silver Valley, specifically metals. Organic compounds that may be present around specific mining and mill sites may be evaluated in the future.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
350 **F27**	11/20/2000	Fred Kirschner Spokane Tribe	Public Draft - July 2000 2-Section 2		2/07/2000	URS Not Accepted

Comments>

8. The COPC concept (page 2-11 and following) is based on the rationale that contaminants are co-located and that cleaning up the major contaminants, originally conceived as excavation, results in excavation of the co-located contaminants. This concept was logical at the time 20 years ago, but it is not as relevant to sites where contaminants have had decades to migrate differentially. In addition, as we learn more about the toxicity of contaminants both individually and in combination, it is clear that eliminating contaminants based on their individual concentrations within individual pathways of exposure results in underestimation of risk, some times by a large amount. The RA as a whole, then, is far from "comprehensive."

Response>>

We disagree. COPCs are not selected based on co-location. The COPCs are selected based on their individual exceedences above background and health-based concentrations in each media of concern. Page 2-11 makes no references to co-location, nor are there any discussions regarding excavation on page 2-11 or subsequent pages in this section.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
351 **F28**	11/20/2000	Fred Kirschner Spokane Tribe	Public Draft - July 2000 2-Section 2		2/07/2000	URS Not Accepted

Comments>

9. It is inadequate and improper to use Region 9 soil PRGs as screening levels. The Region 9 PRGs assume no existing groundwater contamination, no future leaching to groundwater, no ecological impacts, no uptake into food, no inhalation of volatiles, and residential (not subsistence) exposure. The factors for dust resuspension may also be unsuitable for the "highly mobile fine material." Using soil PRGs as a screening tool, then, assumes that some pathways are nonexistent, which results in screening out contaminants that may in fact be posing considerable risk via the pathways that are omitted. They are certainly not suitable for use in evaluating risks to tribal members.

Response>>

We disagree. The use of the Region 9 PRGs appropriately selects chemicals for HHRA evaluation per US EPA guidance. Ecological impacts are evaluated in the ecological risk assessment and potential leaching to groundwater is evaluated in both the RI and FS reports. Uptake into food was examined for both garden vegetables and fish -- these media were not screened. No volatiles were evaluated in this HHRA, see response to Comment F26; however, we note that the Region 9 PRGs include the inhalation pathway for all chemicals. See also response to Comment F22 regarding subsistence exposures. Subsistence pathways were identified as a risk in the HHRA.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
352 **F29**	11/20/2000	Fred Kirschner Spokane Tribe	Public Draft - July 2000 2-Section 2		2/07/2000	URS Not Accepted

Comments>

10. If a screening process is used (and it is preferable not to screen out any contaminants that are detected), it should be on a risk basis, not a regulatory basis. In other words, a full multipathway CSM must be used and contaminants screened out if they contribute individual risk levels of some TBD fraction of a total cancer and non-cancer risk. It is likely that contaminants have been improperly been screened out of the analysis. Mercury should be included regardless of its relation to the SV or PRG.

Response>>

We disagree. Selection of COPCs followed USEPA guidance. Mercury was retained as a COPC in surface water and in fish where it was identified as a potential hazard. The potential underestimation of risk from screening out chemicals is discussed in Section 7. See response to Comment F22, F27, and F28.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
353 **F30**	11/20/2000	Fred Kirschner Spokane Tribe	Public Draft - July 2000 3-Section 3		2/07/2000	URS Not Accepted

Comments>

11. After screening out contaminants, the problem is further compounded by screening out entire pathways (section 3.2.2).

Response>>

Screening out pathways that will not make a significant impact on risks and/or which cannot be quantified for some reason follows US EPA guidelines for risk assessment. The reasons for the exclusion of some pathways are clearly explained in Section 3.2.2. Potential underestimation of risk from screening out pathways is discussed in Section 7.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
354 **F31**	11/20/2000	Fred Kirschner Spokane Tribe	Public Draft - July 2000 2-Section 2		2/07/2000	URS Not Accepted

Comments>

12. The entire background argument is irrelevant to risk. The receptor does not know whether exposure is background or source-derived. Background should never be subtracted from the risk assessment numbers. It is only relevant when risk management actions are chosen.

Response>>

We disagree. Background concentrations were appropriately used as part of the screening process to select COPCs. USEPA guidance requires a comparison to background as part of the selection of COPCs process. If chemical concentrations do not exceed background concentrations, then the chemical is not selected because concentrations have not been impacted by site activities (in this case, mining). The reviewer is incorrect in stating that background was "subtracted" from the risk assessment numbers. Once a chemical is selected, background concentrations are not "subtracted" from the risk equations.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
355 **F32**	11/20/2000	Fred Kirschner Spokane Tribe	Public Draft - July 2000 2-Section 2		2/07/2000	URS Not Accepted

Comments>

13. The relation of background, detection limits and risk-based values is important, but the discussion in Section 2.4.2 of medium-by-medium (or pathway-by-pathway) and contaminant-by-contaminant approach serves only to eliminate contaminants for the convenience of the assessor. The total (cumulative) risk goals from the receptor's perspective are not stated.

Response>>

We disagree. The HHRA appropriately followed US EPA risk assessment guidance which requires that risk assessments focus on the chemicals that will drive risks and thus provide relevant and crucial information to the risk manager. EPA's 1989 Risk Assessment Guidance for Superfund states on page 5-23:

"The objective of the screening procedure is to identify the chemicals in a particular medium that -- based on concentration and toxicity -- are most likely to contribute significantly to risks calculated for exposure to that medium, so that the risk assessment is focused on the "most significant" chemicals."

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
356 **F33**	11/20/2000	Fred Kirschner Spokane Tribe	Public Draft - July 2000 2-Section 2		2/07/2000	TG Not Accepted

Comments>

14. The selection of the screening process, the risk goals, and so on, should have been the subject of government to government discussion at the study design step. The result is a draft risk assessment that fails to consider tribal risks from start to finish.

Response>>

The HHRA disagrees with this comment. The area of investigation scenarios and exposure pathways addressed was determined jointly by the EPA, State and Coeur d'Alene Tribe. Subsistence scenarios and relevant exposure factors were developed in cooperation with Coeur d'Alene Tribe representatives. The Traditional and Current Subsistence scenarios were requested by the Tribe as representing possible future uses of the geographic area addressed in the HHRA. Exposure factors were derived specifically for the Coeur d'Alene Tribe. Scenarios and exposure factor analysis were patterned after the development of similar scenarios for the Columbia River Tribes. A cultural anthropologist, working for the Coeur d'Alene Tribe, reviewed and suggested appropriate modifications for each of the exposure factors.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
357 **F34**	11/20/2000	Fred Kirschner Spokane Tribe	Public Draft - July 2000 1-Section 1		2/07/2000	TG Partially Accepted

Comments>

Receptor Definitions

1. Page 1-5 (Section 1.2) identifies children as age 1-9, adults as females between 17-49, and everyone else as the remainder. This is not standard risk assessment identification, although for lead by itself it makes some sense. However, for a general risk assessment, additional categories need to be used: infants, children aged 1-6, elders, and so on.

Response>>

The HHRA agrees with this comment. References to and discussions regarding susceptible sub-populations are included in Sections 3.1 and 3.2 of the HHRA.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
358 **F35**	11/20/2000	Fred Kirschner Spokane Tribe	Public Draft - July 2000 2-Section 2		2/07/2000	TG Not Accepted

Comments>
2. Section 2.1.3. Did the Coeur d'Alene Tribe have an opportunity to define some of the human exposure areas? Did they agree that only two areas (the mouth of the C d'A River and the lower basin-chain lakes area) would be used with subsistence exposure factors?

Response>>
Please see response to Comment F33 and General Response to Comments, #6a.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
359 **F36**	11/20/2000	Fred Kirschner Spokane Tribe	Public Draft - July 2000 3-Section 3		2/07/2000	TG Not Accepted

Comments>
Subsistence Exposure Scenarios

1. The Current Subsistence scenario uses 61 days/year, assuming that the warmest two months are spent traditionally - does the Coeur d'Alene Tribe agree?

Response>>
Please see response to Comment F33 and General Response to Comments, #6a.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
360 **F37**	11/20/2000	Fred Kirschner Spokane Tribe	Public Draft - July 2000 3-Section 3		2/07/2000	TG Not Accepted

Comments>
2. The Current Subsistence scenario uses 170 g/d for fish consumption (and a similarly reduced number for children) - does the Coeur d'Alene Tribe agree with these consumption rates.

Response>>
Please see response to Comment F33 and General Response to Comments, #6a.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
361 **F38**	11/20/2000	Fred Kirschner Spokane Tribe	Public Draft - July 2000 3-Section 3		2/07/2000	TG Accepted

Comments>
3. The omission of pathways means that the risks are underestimated, not "conservative" (which usually refers to overestimation in the risk community; page 3-33, bottom).

Response>>
The HHRA agrees with this comment. The text will be modified in the final document.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
362 **F39**	11/20/2000	Fred Kirschner Spokane Tribe	Public Draft - July 2000 6-Section 6		2/07/2000	TG Partially Accepted

Comments>
Health Risks

1. Lead risks are treated entirely separately even though many metals have neurologic effects. This results in an understatement of risks.

Response>>
The HHRA agrees with this comment. Please see response to comment F6.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
363 **F40**	11/20/2000	Fred Kirschner Spokane Tribe	Public Draft - July 2000 6-Section 6		2/07/2000	TG Partially Accepted

Comments>
2. The CDC PbB recommendation (95% <10 ug/dL) is used as the threshold to identify risk potential risk. This threshold is much higher and therefore less protective than the threshold used by the Spokane Tribe.

Response>>
The HHRA is unaware of Spokane Tribe thresholds and has not included any that might differ from those of other governments in this document.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
364 **F41**	11/20/2000	Fred Kirschner Spokane Tribe	Public Draft - July 2000 4-Section 4		2/07/2000	URS Not Accepted

Comments>
3. The GI absorption needs to be carefully examined, particularly the bioavailability rates of arsenic (Section 4.3 and 7.3.2).

Response>>
GI absorption was assumed to be 100 percent for all chemicals except arsenic. Assuming 100 percent is health-protective. For arsenic, the EPA considers there is sufficient information to depart from the default assumption of 100 percent. This information was discussed in Sections 3, 4, 7, and in Appendix I which contains detailed toxicity profiles for each chemical of concern.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
365 **F42**	11/20/2000	Fred Kirschner Spokane Tribe	Public Draft - July 2000 5-Section 5		2/07/2000	URS Accepted

Comments>
4. Of the 7 COCs, only two were evaluated for dermal exposure.

Response>>
The HHRA agrees with this comment. These chemicals were selected on the basis of potential adverse effects by exposure route. The other COPCs were not considered to have significant adverse health effects by the dermal pathway for the conditions of exposure in the CdA basin.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
366 **F43**	11/20/2000	Fred Kirschner Spokane Tribe	Public Draft - July 2000 4-Section 4		2/07/2000	URS Not Accepted

Comments>
5. Section 4.1.2 says that only oral RfDs were used - does this mean that inhalation of resuspended dust was not included?

Response>>
Yes. See sections 2.5.6 and 3.2.2. Inhalation of fugitive dust was not quantitatively evaluated for the non-lead metals.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
367 **F44**	11/20/2000	Fred Kirschner Spokane Tribe	Public Draft - July 2000 4-Section 4		2/07/2000	URS Not Accepted

Comments>
6. The information in Section 4.3 on individual contaminants say that many are poorly absorbed, but the assumptions used in the RA are not given.

Response>>
The use of the gastrointestinal absorption factor is discussed on page 3-47. As the text states, a correction factor was used for arsenic only and a detailed discussion follows on why the 60% factor was chosen. For all of the other chemicals, no correction factor was used therefore 100% absorption was assumed. See also response to Comment F41.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
368 **F45**	11/20/2000	Fred Kirschner Spokane Tribe	Public Draft - July 2000 4-Section 4		2/07/2000	TG Accepted

Comments>
7. There is additional information on lead that is not included in Table 4-2, such as behavioral effects at low exposure levels. Also, please include information on population blood lead levels in uncontaminated areas (it is at or below 5 ug/dL) to avoid the implication that 10 ug/dL is a NOAEL.

Response>>
The HHRA agrees with this comment. Additions to the Table will be considered for the final document.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
369 **F46**	11/20/2000	Fred Kirschner Spokane Tribe	Public Draft - July 2000 5-Section 5		2/07/2000	URS Partially Accepted

Comments>
8. Section 5.3 should emphasize two additional points: that not all contaminants were carried through the assessments and that lead is not included in the noncancer hazard discussion on hazard index.

Response>>
Section 5 will be amended for the subsistence section to indicate the potential for additional chemicals of concern. The non-carcinogenic effects of lead are addressed in Section 6, not in Section 5 because lead lacks a reference dose. See also resonse to Comment F6.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
370 **F47**	11/20/2000	Fred Kirschner Spokane Tribe	Public Draft - July 2000 6-Section 6		2/07/2000	TG Not Accepted

Comments>

9. Separation of the lead exposure into that received from residence (yard, garden, commercial foods obtained from elsewhere, housepaint) from that received from additional incremental exposure through recreational and occupational exposure may be a problem if this information is used to allocate risk management goals. A more logical way to define baseline in this case might be to separate housepaint and commercial food obtained from non-local sources from all source-derived exposure. Then, the PRG would be set assuming that paint-food exposures are ubiquitous and uncontrollable, so the soil PRG must be more stringent.

Response>>

The HHRA disagrees with this comment. The HHRA evaluates the potential human health risks associated with contaminated environmental media. The lead analysis examines the effects of soil and dust lead on blood lead levels in concert with dietary and other sources. There is little indication of direct ingestion of paint particulate aside from that of lead paint incorporated in the soil and dust pathway. The site-specific analysis uses observed soil and house dust lead levels. As a result, the sources of lead to dust, such as paint, yard soils, materials tracked in by workers, fugitive dusts, etc. are inherent in the analysis. The influence of lead paint on these pathways is examined by regression analysis. The interpretation of these results was that contaminated soils, house dust, and lead based paint are all related to excess absorption. See also General Response to Comments, #4a, #5a, and #7a.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
371 **F48**	11/20/2000	Fred Kirschner Spokane Tribe	Public Draft - July 2000 6-Section 6		2/07/2000	TG Not Accepted

Comments>

10. Since Native American subsistence exposures were estimated to be too high for the IEUBK to run properly, how will this information be used to set PRGs, especially since tribal blood lead values currently are not available? At what point does the IEUBK certainty diverge from an acceptable level?

Response>>

IEUBK analysis of subsistence lead intake could become relevant at levels resulting in blood lead concentrations in the 20 ug/dl to 30 ug/dl range and below. This would occur at media concentrations substantially less than those observed today. Blood levels below health criteria are unlikely to occur until media concentrations approach background levels. However, this assumes that the bio-kinetic portion of the model is applicable to individuals practicing subsistence lifestyles. The HHRA is unaware of any data or investigations regarding absorption factors for subsistence lifestyles.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
372 **F49**	11/20/2000	Fred Kirschner Spokane Tribe	Public Draft - July 2000 6-Section 6		2/07/2000	TG Not Accepted

Comments>

11. Are we going to get into an argument about whether the Box or Default Model is more applicable in different parts of the Valley? How can this be prevented?

Response>>

Please see General Response to Comments, #9.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
373 **F50**	11/20/2000	Fred Kirschner Spokane Tribe	Public Draft - July 2000 3-Section 3		2/07/2000	TG Accepted

Comments>

Other Comments

1. The area use (page 3-2) does not mention tribal use. Other than this omission, the demographic description is much better than usual.

Response>>

The text will be amended for the final document.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
374 **F51**	11/20/2000	Fred Kirschner Spokane Tribe	Public Draft - July 2000 3-Section 3		2/07/2000	URS Partially Accepted

Comments>

2. Section 3.1.4. "some residents will be exposed to lower concentrations in their homes than others." How is the range of test results used? It would be useful to at least have a reference to the uncertainty section and to the results that are presented as ranges.

Response>>

The intent of this section is to indicate that concentrations in individual homes are variable and that risks for non-lead are estimated by geographical area and not by individual home. The only ranges of risks estimated are for the reasonable maximum exposure scenario (RME) versus the central tendency (CT) scenario. RME and CT results are both presented in Section 5. The text in Section 3 will be clarified.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
375	11/20/2000	Fred Kirschner	Public Draft - July 2000		2/07/2000	TG
F52		Spokane Tribe	3-Section 3			Accepted

Comments>

3. It would be useful to have tables showing the various locations, the relevant exposure scenarios, and the contaminant concentrations. Without this, it is hard to tell how the environmental data were used (average? maximum? distribution?) with which pathways and scenarios.

Response>>

The HHRA agrees with this comment. All the assumptions are included in various Tables throughout the document. A summary table will be added to the final document to consolidate the presentation.

Misc. Input>>

Private Individuals

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
376	12/08/2000	Justin Rice-Wallace	Public Draft - July 2000		2/08/2000	TG
G1		Private Individual	0-Executive Summary			Not Accepted

Comments>

After reviewing the Human Health Risk Assessment (HHRA) Executive Summary it doesn't appear to fairly represent what I see occurring in my community. I have lived here for many years, and I believe the risk from lead exposure is minimal. The Environmental Protection Agency and the HHRA have completely overestimated the exposure that my children and I face living in the Silver Valley.

I understand that the HHRA has not taken into consideration the amount of time children are actually exposed to lead in their environment. There is a great deal of speculation and many assumptions that went into preparing the HHRA. Did you take into consideration that children don't habitually play on waste rock piles, that there is snow on the ground for six months of the year, and that children don't eat large quantities of fish from the river, bones and all? You assume that local children are playing for days, weeks and months on the sandy beaches along the river. You assume that they eat garden vegetables on a regular basis that are full of lead.

Response>>

The HHRA disagrees with this comment. The assumptions used in the HHRA are based on consensus reviews of scientific research and collaboration with national experts in the field of lead, and human health risk assessment. The HHRA does consider that children do not habitually play on waste rock piles, and that many areas are not available during a large portion of the year due to snow and other variables. For example, the predicted Reasonable Maximum Exposures for children playing on Upland Parks was based upon two visits per week for 34 weeks per year. Default dietary intake rates representing the typical US market basket are included in both model forms. National default values are used for baseline dietary intake rates throughout these analyses. Discussion of incremental lead intake rates from home grown produce and recreational fish consumption is discussed in section 6.3.1. The fish ingestion pathway evaluated for the tribal scenarios is based on filleted tissue metals data from a limited number of species from the lateral lakes and whole fish from the Spokane River. Fish ingestion for the resident population is based on fillet data from the lateral lakes. These results are likely not representative of fish from
Lake Coeur d'Alene and extrapolation of hazards and risks to the Lake Coeur d'Alene fishery is not recommended. Garden vegetable lead levels are based on actual samples collected in the Basin. See also General Response to Comments, #5 and #7.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
377	12/08/2000	Justin Rice-Wallace	Public Draft - July 2000		2/08/2000	TG
G2		Private Individual	0-Executive Summary			Not Accepted

Comments>

What I really don't understand is why you assume that the exposure comes mainly from soils. What about the paint in my home and other homes in the Valley, most of which were built long before the 1970's Isn't that lead paint?

Response>>

The HHRA disagrees with this comment. Lead from paint is discussed in Section 6.3.4, and specific studies regarding lead-based paint in the Coeur d'Alene River Basin are cited. Table 6-13 shows summary statistics for lead-based paint by geographic subarea, and Figures 6-7a and 6-7b show mean interior and exterior paint lead concentrations by geographic area. Extensive site-specific analysis was conducted regarding the relationships between blood, soil, paint, and dust lead levels. The interpretation of these results in the HHRA was that contaminated soils, house dust, and lead based paint are all related to excess absorption. Overall this suggests complex exposure pathways, with blood lead levels most related to dust lead loading in the home, followed by independent effects of yard soil lead, interior paint lead condition, and exterior paint lead content. The dust lead pathway is most influenced by outdoor soils, augmented by paint contributions in older homes, especially those in poor condition. See also General Response to Comments, #3 and #4.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
378	12/08/2000	Justin Rice-Wallace	Public Draft - July 2000		2/08/2000	TG
G3		Private Individual	0-Executive Summary			Not Accepted

Comments>

I really don't understand why you can't just check all the children instead of these small sample groups that don't represent the entire Valley. The HHRA states that our communities are pretty impoverished. Yet, if you compare us on a national level, our children have the same blood lead levels as children who live in similar conditions. So why are we being singled out to look like we are worse off?

Response>>

Testing the blood lead of every child in the Basin is unrealistic as mandatory compliance could not be compelled under State law. However, the Panhandle Health District (PHD) has an extensive promotional effort to inform and encourage voluntary testing of all children (ages 9 months through 9 years) throughout the Basin. One week prior to field activities, the program and the project schedule are advertised in area newspapers and on the radio. A bulk mailing was also sent to every house in the basin advertising the blood lead program. A phone number is provided so those who wish to participate can contact the project office. However, not all parents will choose to have their child tested. See also General Response to Comments, #1a and #2a.

There is a divergence of opinions regarding the appropriate comparisons between the National and State-wide Lead absorption databases with the results of the HHRA. Comparisons are difficult for the following reasons: 1) scientific designs of the NHANES surveys are constructed in a way that does not permit valid comparisons with results of blood lead distributions for a given community, and 2) the design for gathering and organization of the Basin data was not for purposes of matching the various demographic and socioeconomic strata in the NHANES III survey reports. If the Basin data was divided into the numerous categories to allow such comparisons, it would produce so few children as to make comparisons with national data meaningless.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
379	12/08/2000	Justin Rice-Wallace	Public Draft - July 2000		2/08/2000	TG
G4		Private Individual	0-Executive Summary			Not Accepted

Comments>

Do you not understand that by playing with our communities as if we were science projects or experiments you paint us in a bad light? Who wants to live in the Valley or vacation here or develop businesses here if they are given a false impression of the health risks to their families? We are proud of our children and our educational system. We have in the past and continue to produce some pretty smart young men and women in this Valley. Instead of using models and tables and assumptions why don't you look around you and see what kind of people really live here. Maybe then you will understand why we are insulted by your actions and believe the HHRA and its supporters are not working in the best interests of the people of the Silver Valley.

Response>>

The HHRA is not intended to insult anyone, but is designed to identify potential pathways for lead and other heavy metal exposure, so that residents of the Basin can be aware of any associated risks, and future decisions can be made to protect human health throughout the Basin. A diversity of opinions has been received from citizens, some believing risk has been overstated, others believing risk is understated, and a few believe risk has been fairly portrayed.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
380	12/08/2000	Frank Frutchey	Public Draft - July 2000		2/08/2000	TG
H1		Private Individual	0-Executive Summary			Not Accepted

Comments>

Thank you for extending the comment period for the HHRA regarding the Coeur d'Alene Basin. After reviewing the information presented to the citizens at the citizens advisory committee, it seems to me the correlation between human blood lead levels in the CDA Basin and the concentrations of lead in the soil does not tie together very well. Children who live and/or play on highly contaminated soils do not necessarily have high blood lead levels; conversely, some children with high blood lead levels do not live on, or near contaminated soils. Therefore, the cause and effect relationship between soil lead levels and human blood lead levels is weak.

In order to more effectively break the pathway of inception, it would be more prudent to investigate the habits of the children with high levels to determine the most practical method of prevention. There may be other sources of lead besides only that in the soil; examples of other sources may be paint, lead containing solder in water pipes, leaking batteries and old tailings piles used as playgrounds.

Response>>

The relationship of soil lead concentrations to blood lead levels is both direct and indirect and exposure can occur away from the home. Indirect exposure to soils can occur when soil becomes entrained in the house dust. Quantitative analysis of these relationships show that yard soil is a major contributor to mat dust lead loading in the home suggesting that yard soils are moving into the house. Mat dust lead loading showed the strongest relationship with blood lead levels (Tables 6-19 and 6-20). See General Response to Comments, #3d and #4.

Children with blood lead concentrations greater than 10 ug/dl are followed up with a nurse visit to investigate all possible sources of exposure. These nurse visits have noted that the majority of the cases of high blood lead levels have been attributed to high soil and dust concentrations either in the residence or from recreational visits. Lead solder and leaking batteries are rarely found to contribute to these cases of high blood leads, whereas lead paint is sometimes a problem. The focus of the nurse follow-up is on the pathways of exposure as well as education about the risks of lead. The PHD's Lead Health Intervention Program provides information and educational tools on the risks of lead exposure and how to decrease a child's exposure to lead in the community.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
381	12/08/2000	Frank Frutchey	Public Draft - July 2000		2/08/2000	TG
H2		Private Individual	0-Executive Summary			Partially Accepted

Comments>

Good hygiene plus re-establishing a good, soil farming vegetative cap on top of leaded soils will in my experience result in lower blood lead levels more quickly and more cost effectively than trying to dig up and safeguard in a repository all the soils with lead levels above EPA's background level.

Also, we who have lived in the CDA Basin for any length of time, know that relatively large amounts of lead, will be moved around alluvially during episodic events. Therefore, it seems futile to me to address the problem of human exposure to lead by digging and removal since several episodic events can occur each decade. In situ treatment of heavy metals in the soil coupled with re-vegetation using an indigenous sod farming grass will in my experience grow up through silt deposited during an episodic event. It is better to work with nature, rather than to struggle against such natural processes.

Response>>

The HHRA agrees that the selection of remedial clean up alternatives should consider these points in developing the Proposed Plan for the Basin.

Misc. Input>>

Community Leaders for EPA Accountability Now (CLEAN)

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
382	10/16/2000	Dee Jameson	Public Draft - July 2000		2/08/2000	TG
I1		CLEAN	0-Executive Summary			Not Accepted

Comments>

Accordingly, we recognize the EPA allowed the State to have the lead on the HHRA, but with it came the Integrated Exposure Uptake Biokinetic Model (IEUBK). The model, based on national defaults does not accurately reflect the conditions present in the Coeur d'Alene River Basin today. It is widely believed the model is not appropriate for evaluating periodic exposure to lead, based in part on the fact that the model grossly overestimates the potential blood-lead level of Basin residents. As such, we respectfully ask the State to modify its plan to allow for actual site-specific conditions - based on the factual data compiled by the Panhandle Health District during the last two decades.

Response>>

The HHRA was accomplished in accordance with pertinent EPA policy and guidance in compliance with the National Contingency Plan. The most recent guidance regarding use of the IEUBK and site-specific blood lead data is found in Appendix O. Both types of analysis are accomplished in the HHRA and the "Box-model" uses site specific data from the Bunker Hill Superfund Site as an input into the IEUBK. In addition, the follow-up investigations on children with high blood lead levels have been summarized in Section 6.2.3 of the HHRA. All of these data and analyses are considered in reaching the findings and conclusions of the document. See also General Response to Comments, #9 and #10.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
383	10/16/2000	Dee Jameson	Public Draft - July 2000		2/08/2000	TG
I2		CLEAN	0-Executive Summary			Not Accepted

Comments>

Outside the BHSS, the State's contractor TerraGraphics is using a cumulative set of blood-lead level (BLL) results (1996-99) for the entire Basin. By doing so, the levels hide the gains made, year by year, during that time. In reality, the 1999 Basin BLL average of 5.3 mg/dl shows that the average blood lead levels in the Basin are already at or near the EPA's remedial action goal.

Response>>

The HHRA disagrees with this comment. Observed blood lead levels have shown little discernable difference in the last four years with respect to mean blood lead levels or the incidence of children to exceed 10 ug/dl. The data shown in Table 6-1 suggest no significant difference among the four years of data, although the poor turnout in some years precludes making valid comparisons. The cumulative data set was used to maximize the number of observations available to support the site-specific analysis and to use actual blood lead levels to the maximum extent practicable in assessing risk in the Basin. Available data indicate that about one-in-four children under two years of age have blood lead levels of 10 ug/dl or greater, and the age adjusted incidence of excess blood lead levels is 16.2% for 1-6 year-old children. This incidence of high blood lead levels is a health concern for these children. There are divergent opinions as to how well the health surveys represent the non-participants and whether comparisons to other national and State populations are appropriate. Comparison of blood lead data for the Basin to other sites and national or State-wide surveys, for the purpose of determining whether these findings are "relatively good or bad", is problematic.

Selection bias may have occurred related to individual family decisions to participate. These opinions are discussed in Sections 6.2.2 and 7.4.1, 8.8, and 8.11.2 and reflect most of the comments offered by reviewers. See also General Response to Comments, #2, #3a and #3b.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
384	10/16/2000	Dee Jameson	Public Draft - July 2000		2/08/2000	TG
I3		CLEAN	0-Executive Summary			Not Accepted

Comments>

The entire population in the Basin is not at risk for lead exposure. We believe only those who may have some prior exposure are at risk, in addition to pregnant mothers and children under two. Your Plan needs to recognize this fact and should apply one set of remedies necessary to the vast majority of the population while developing another set for those may be at risk.

As an example, education programs for those families at risk on how to avoid further contamination make much more sense than dramatic physical remedies. Also keep in mind, the Agency for Toxic Substances Disease Registry (ATSDR) has already determined that fish consumption does not need to be curtailed from fish caught in the lateral lakes of the Coeur d'Alene River basin.

Further, the IEUBK model is also based on exposure scenarios that are unrealistically conservative. For example, it is assumed that young children are bare-foot and wear shorts and short-sleeved shirts from April through November in the River Basin, consume 25g/day of fish caught locally year round, and consume 8 g/day locally grown garden vegetables year round.

Response>>

The HHRA assesses risk for a variety of sub-populations, pathways and exposure sources and excessive risk is identified on an age-specific basis. Remedial strategies and clean up criteria developed under risk management activities will consider this information and address those populations at unacceptable risk levels. Homegrown vegetable ingestion rates are explained on page 3-48. A wet-weight vegetable ingestion rate of 5.04 g per kg body weight per day for the RME case and 0.492 g/kg-day for the CT case were selected, based on the U.S. Department of Agriculture Nationwide Food Consumption Survey (NFCS). Ingestion rates for fish are explained on page 3-52. A fish ingestion rate of 46 g/day was selected based on national fish portion sizes (USEPA 1997a) and information from a local fish consumption survey (ATSDR 1989). Further response is covered in General Response to Comments, #8a and #9a.

Misc. Input>>

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
385	10/16/2000	Dee Jameson	Public Draft - July 2000		2/08/2000	TG
I4		CLEAN	0-Executive Summary			Not Accepted

Comments>

The Human Health Risk Assessment (HHRA) focuses primarily on soil-lead contamination without accepting other exposure scenarios, including lead-based paint in the Silver Valley's pre-1970's homes. It further fails to compare actual blood lead levels in the Silver Valley population with those expected to be found in any population of similar economic and housing characteristics.

For example, a comparison to national and state-wide blood lead levels show that the geometric mean of BLL's for the Basin in 1999 (1-6year olds) at 5.2 mg/dl is lower than National (1991-94) low-income, pre-1946 housing BLL's of 5.5 mg/dl. The same category for percentage of children equal or greater than the 10 mg/dl (CDC standard) is also below the national level.

Response>>

The HHRA disagrees with this comment. Analysis conducted in the HHRA suggest that yard soils are a primary source of lead absorption among children both through direct contact and as a contributor to lead in house dust. Other sources including lead paint are also identified as sources to both blood and dust lead. The HHRA concludes that both sources present excessive risk and provides example analysis regarding potential cleanup criteria. Lead from paint is discussed in Section 6.3.4, and specific studies regarding lead-based paint in the Coeur d'Alene River Basin are cited. Table 6-13 shows summary statistics for lead-based paint by geographic subarea, and Figures 6-7a and 6-7b show mean interior and exterior paint lead concentrations by geographic area.

There is a divergence of opinions regarding the appropriate comparisons between the National and State-wide Lead absorption data bases with the results of the HHRA. Making actual comparisons is difficult as the scientific designs of the NHANES surveys are constructed in a way that does not permit valid comparisons with results of blood lead distributions for a given community, and the design for gathering and organization of the Basin data was not for purposes of matching the organization of the various demographic and socioeconomic strata in the NHANES III survey reports. If the Basin data was divided into the numerous categories to allow such comparisons, it would produce so few children as to make comparisons with national data meaningless. See also General Response to Comments, #2.

Misc. Input>>

Comments Summary

ID	Date	Comment By/Org	Document Version/Section	SubSection/Add'l Ref	Response Due	Response By/Type
386	10/16/2000	Dee Jameson	Public Draft - July 2000		2/08/2000	TG
I5		CLEAN	0-Executive Summary			Not Accepted

Comments>

Basin Blood lead testing needs to be done more than once a year. By taking those tests only in August when exposure levels are the greatest, results are skewed high. There should be multiple testing periods each year to get a more accurate reflection of levels/averages. Further, the State should consider following the Shoshone Natural Resources Coalition effort of "finger-prick" testing methods to reduce parents' and children's fear or apprehension of getting tested.

Response>>

Blood lead testing was purposely accomplished during the peak season, as the objective of the program is to identify children with excessive blood lead levels. There are seasonal variations in blood lead levels, but it is important to identify children at risk during the peak exposure period as these levels are of health concern. Experience at the BHSS has shown that conducting winter screens has diminished the turnout during the subsequent year when children can most benefit from the service. See further discussion under General Resonse to Comments, #2.

Misc. Input>>